

A randomised controlled trial comparing erector spinae and transversus abdominis plane blocks for postoperative analgesia after elective caesarean section

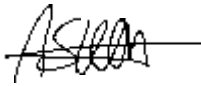
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Master of Medicine in the branch of Anaesthesiology

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Declaration

I, Aidan Eksteen, herewith declare that this research report is my own, unaided work. It is being submitted for the degree of Master of Medicine at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.



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Abstract

Background

Peripheral abdominal nerve blocks contribute to multimodal postoperative analgesia that enhances early recovery after caesarean sections. The transversus abdominis plane (TAP) block is an established technique that offers somatic abdominal analgesia. The erector spinae plane (ESP) block is a novel fascial plane block that may offer additional visceral analgesic effects. This study aimed to compare the postoperative analgesic efficacy of bilateral ultrasound-guided TAP blocks to ESP blocks in women undergoing caesarean sections under spinal anaesthesia

Methods

Sixty-six ASA grade 1-3 (≥ 18 years) patients undergoing elective caesarean section under spinal anaesthesia were randomly allocated to receive either TAP blocks ($n = 33$) or ESP blocks at the T9 vertebral level ($n = 33$). The primary outcome measure was 24-hour cumulative morphine consumption. The secondary outcomes included the time taken to perform blocks, numeric rating scale (NRS) pain scores at 6- and 24-hours, effect of pain on activities of daily living (ADLs) and care for the newborn, time to first analgesic request, severity of opioid-related side effects, and patient satisfaction.

Results

There was no statistically significant difference in mean (SD) 24-hour cumulative morphine consumption between the ESP blocks and TAP blocks: 27 mg (14) vs 32 mg (15) ($p=0.185$). ESP blocks took longer to perform: 10.7 minutes (2.2) vs 9.0 minutes (2.5) ($p<0.01$). There were no significant differences in the other secondary outcomes.

Conclusion

The TAP block and ESP block were equally effective for postoperative analgesia after elective caesarean section under spinal anaesthesia. The ESP block did not demonstrate significant additional visceral analgesic effects.

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Table of Contents

Declaration.....	ii
Abstract.....	iii
Acknowledgements	iv
List of figures	viii
List of tables	ix
Abbreviations	x
Statement	xi
Section 1: Review of the literature	1
1.1 Introduction.....	1
1.2 Pain	2
1.2.1 Definition	2
1.2.2 Physiology.....	2
1.2.3 Postoperative Pain.....	3
1.2.4 Caesarean section pain anatomy	3
1.2.5 Consequences of poorly controlled pain	4
1.2.6 The experience of caesarean section pain	4
1.3 Management of postoperative pain.....	5
1.3.1 Multimodal analgesia	5
1.3.2 Neuraxial anaesthesia.....	5
1.3.3 Intrathecal opioids.....	5
1.4 Peripheral Abdominal Nerve Blocks	6
1.4.1 Clinical importance	6
1.4.2 Techniques	7
1.4.2.1 Transversus abdominis plane (TAP) block	7
1.4.2.2 Ilioinguinal & Iliohypogastric (II-IH) block	7
1.4.2.3 Continuous wound infusion (CWI)	8
1.4.2.4 Quadratus lumborum (QL) block	8

1.4.2.5 Erector spinae plane (ESP) block.....	8
1.4.3 Comparison between block techniques.....	9
1.4.4 Peripheral abdominal nerve blocks in Southern Africa	10
1.5 Summary.....	10
1.6 References	11
Section 2: Author's guidelines	22
Section 3: Draft Article.....	38
Section 4: Proposal	64
4.1 Introduction	65
4.2 Problem Statement.....	68
4.3 Aims	69
4.4 Objectives	69
4.5 Research Assumptions.....	69
4.6 Demarcation of the Study Field.....	71
4.7 Ethical Considerations.....	71
4.8 Data Collection	72
4.8.1 Research Design	72
4.8.2 Study Population	73
4.8.3 Study Sample	73
4.8.3.1 Sample method	73
4.8.3.2 Sample size	73
4.8.3.3 Inclusion and exclusion criteria.....	73
4.8.4 Collection of Data.....	74
4.9 Data Analysis.....	77
4.10 Significance of the Study.....	77
4.11 Validity and Reliability of the Study.....	78
4.12 Potential limitations.....	79
4.13 Project outline.....	80

4.14 Financial plan	80
4.15 References	81
4.17 Appendices	88
4.17.1 Appendix A	88
4.17.2 Appendix B.....	89
4.17.3 Appendix C.....	91
4.17.4 Appendix D	94
4.17.5 Appendix E.....	95
4.17.6 Appendix F	96
4.17.7 Appendix G	97
4.17.8 Appendix H	98
Section 5 Annexures.....	104
5.1 Ethical Approval.....	104
5.2 Graduate studies approval	105
5.3 Turnitin Report	106

LIST OF FIGURES

Figure 3.1: Consolidated Standards of Reporting Trials flow diagram of patient selection ... 49

Figure 3.2: Mean (SD) 24-hour cumulative morphine dose administered via PCA device after
Caesarean section surgery 51

LIST OF TABLES

Table 1: Patient, anaesthetic, and surgical characteristics	50
Table 2: Pain scores, pain interference, and patient satisfaction	52
Table 3: Opioid-related side effects	53

LIST OF ABBREVIATIONS

AE	Researcher Aidan Eksteen
ASA	American Society of Anesthesiologists
BMI	Body mass index
CONSORT	Consolidated Standards of Reporting Trials
CI	Confidence interval
CS	Caesarean section
ECG	Electrocardiogram
ERAS	Enhanced recovery after surgery
ESP	Erector spinae plane block
IU	International units
IV	Intravenous
JW	Researcher Janine Wagner
NIBP	Non-invasive blood pressure
NRS	Numeric rating scale
PCA	Patient controlled analgesia
PI	Principal investigator
PK	Researcher Peter Kamerman
RCT	Randomised controlled trial
RMMCH	Rahima Moosa Mother and Child Hospital
RSA	Republic of South Africa
SASA	South African Society of Anaesthesiologists
SD	Standard deviation
TAP	Transversus abdominis plane block
TK	Researcher Thomas Kleyenstuber
TP	Transverse process
VAS	Visual analogue scale

Statement

The Research Report consists of a literature review, author's guidelines, draft article, study proposal, and annexures. The study proposal is included for background reference and is not for examination.

The formatting of this Research Report complies with the University of the Witwatersrand's Style Guide for Theses, Dissertations and Research Reports. The formatting of the draft article complies with the author's guidelines of *Regional Anesthesia and Pain Medicine*, the journal to which it is intended to be submitted and may therefore differ from the rest of the Research Report. These differences include the referencing style, margins, font, numbering of figures and tables, and word count.

Section 1: Review of the literature

1.1 Introduction

The caesarean section is one of the most frequently performed surgical procedures worldwide (1). Caesarean section rates in the South African public sector have increased from 15.1% to 24.1% from 2006 to 2017, with private sector rates reaching 75% (2). Caesarean sections are associated with moderate to severe pain in the postoperative period and rank in the top ten surgical procedures for pain severity (3–5). Thus, an increasing number of women are being exposed to surgical procedures with significant pain intensity. Poorly controlled postoperative pain has dire consequences for individual patients and can become a public health problem associated with higher healthcare costs (6).

Adequate postoperative analgesia is essential to avoid a multitude of negative sequelae for the mother and infant after a caesarean section. However, there is still a high incidence of poorly controlled postoperative pain (7–9). The reason for this is multifactorial but good postoperative pain control begins with initiating an evidence-based and personalised intraoperative analgesic regimen (10,11). This analgesic plan needs to employ a multimodal approach with the use of different analgesic agents that inhibit different levels of the pain pathways, thus improving the quality of analgesia and limiting side effects associated with the analgesics (12).

Multiple international guidelines make recommendations on multimodal analgesic regimens for caesarean sections (13–15). Peripheral abdominal nerve blocks form one of the recommended components of these regimes. Peripheral abdominal nerve blocks can be utilised in patients receiving both general and neuraxial anaesthesia. These techniques have many advantages such as reduction in postoperative pain scores, reduced opioid consumption, and improved patient satisfaction (16). Additionally, they have very few side effects and are safe to perform in skilled hands, especially under ultrasound guidance (17,18). Whilst certain techniques such as the transversus abdominis plane (TAP) block have been extensively studied and are recommended by international guidelines, recent studies have begun to compare newer techniques such as quadratus lumborum (QL) and erector spinae plane (ESP) blocks to their predecessors (13,19–21).

Whilst there are promising results for these regional anaesthetic techniques in enhancing pain control in caesarean section patients, there is a paucity of data among African women as to the preference and superiority of these techniques.

To date, there have been no studies to compare different peripheral nerve block techniques for postoperative analgesia after caesarean sections in South African women.

1.2 Pain

1.2.1 Definition

Pain is defined by the International Association for the Study of Pain (IASP) as “An unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage” (22). It comprises an objective component which is a physiological stimulus created in response to a noxious stimulus, and a subjective component which is the emotional and psychological experience associated with this stimulus. Pain can be classified according to its source of origin and its duration. Nociceptive pain occurs as a result of stimulation of specialised sensory afferents known as nociceptors in response to actual or potential tissue damage, whereas neuropathic pain results from direct injury to nerve tissue (23). Acute pain usually exists for an appropriate time frame after the noxious insult to the body, whereas chronic pain is defined as pain that persists beyond the usual course of an acute disease or after a reasonable time for healing to occur (24). Acute pain can be further divided into having somatic or visceral origin. Somatic pain is derived from skin, subcutaneous tissue, muscles, tendons and bones, and tends to be sharp and well localised, whereas visceral pain arises from internal organs and their coverings and tends to be dull and poorly localised (23).

1.2.2 Physiology

Pain pathways are complicated but can be broken down into ascending and descending pathways that facilitate the four main physiologic steps of pain namely transduction, transmission, modulation, and perception (23,25,26). The ascending pathways transduce and transmit a noxious impulse from a site of injury, up to the dorsal horn of the spinal cord, then onto the thalamus and further to the somatosensory cerebral cortex (23,25,26). Pain transduction is facilitated by the interplay of sensory afferent fibres responding to a noxious stimulus with various chemical mediators acting locally to enhance this signal. This inflammatory soup of chemicals such as substance P, leukotrienes, prostaglandins, histamine, bradykinin, and serotonin, contribute to enhancing signal transduction of a noxious stimulus via mechanical, thermal, chemical, polymodal, and silent nociceptors (27). They also mediate local tissue response to injury such as swelling and erythema (23,25). Descending pathways facilitate modulation of pain signals transferred to the spinal cord and brain from the site of stimulus thus playing a key role in the perception of pain.

Inhibitory and excitatory neurons at the dorsal horn of the spinal cord are key in the amplification or dampening of pain signals that contribute to pain severity and the development of chronic pain (23,25,26).

1.2.3 Postoperative Pain

Surgical incision and tissue distortion result in a cascade of noxious stimuli being produced which causes profound activation of nociceptors both peripherally and centrally. There is a massive production of pro-inflammatory mediators which further amplify these pain signals (25,26). Left untreated, this process will lead to peripheral and central hypersensitisation and wind-up which results in hyperalgesia, allodynia, and potentially chronic pain (28). This explains the need for anaesthetists to provide sufficient analgesia to limit the extent of acute pain and further prevent its progression to more severe pain states and chronic pain. A multimodal approach that blocks the pain pathways at multiple sights is the most effective technique (28).

1.2.4 Caesarean section pain anatomy

Caesarean section involves incision through multiple layers that have sensory nerve endings for pain. Somatic pain is derived from incision and stretch through layers of the anterior abdominal wall that includes skin, subcutaneous tissues, muscle layers, and fascia. Visceral pain is derived from incision and stretching of the parietal and visceral peritoneum, incision and traction on the uterus and associated structures such as the bladder, as well as pressure on the diaphragm (29).

The anterior abdominal wall receives innervation from the anterior rami of the lower thoracic and lumbar spinal nerve roots from T7 to L1. The nerves arising from these roots include the thoraco-abdominal nerves from T7 to T11, the subcostal nerve from T12, and the ilio-hypogastric and ilio-inguinal nerves from L1 (30). These nerves are extensions of the intercostal nerves. Below the costal margin at the mid-axillary line, they pierce into the abdominal wall between the transversus abdominis and internal oblique muscle layers, which is a neurovascular plane known as the transversus abdominis plane (TAP). The nerves traverse towards the midline and give off multiple branches that form upper and lower TAP plexuses that supply sensory innervation to the anterior abdominal wall. The nerves originating from T9 to L1 are responsible for sensory innervation from the umbilicus down to the inguinal crease, which are the areas most involved during a caesarean section (30,31).

Visceral structures such as the uterus receive sensory innervation from branches of the sympathetic and parasympathetic autonomic nervous system. The body of the uterus receives mainly sympathetic fibres via the inferior and superior hypogastric plexuses and lumbar splanchnic nerves which arise from T10 to L1, whereas the cervix receives parasympathetic fibres from the S2 to S4 levels (32) .

1.2.5 Consequences of poorly controlled pain

Intraoperative and postoperative pain are leading concerns for patients undergoing caesarean section and are a major determinant of overall patient satisfaction (33). Pain is associated with numerous neuroendocrine effects, which adversely affect the physiology of the central nervous, cardiovascular, respiratory, and gastrointestinal systems (34). Severe pain may reduce the ability of the mother to bond with and care for the infant and initiate breastfeeding successfully (7). Several postoperative complications are associated with pain such as delayed ambulation, impaired oral intake, ileus, inadequate respiration, atelectasis, pneumonia, thromboembolic events and depression (11). In addition, it may contribute to hyperalgesia, chronic post-surgical pain (CPSP), post-traumatic stress disorder (PTSD), and postpartum depression (35,36). Studies have shown that up to 18% of patients develop chronic pain after caesarean section, with the severity of acute postoperative pain being a major predictor thereof (3,35). These patients are at further risk of chronic opioid use and dependence (37).

1.2.6 The experience of caesarean section pain

The experience of pain is highly subjective and variable between individuals. Pain is affected by physiological, psychological, social, educational, ethnic and cultural factors (34,38). The caesarean section carries a relatively high incidence of poorly controlled postoperative pain, which may be worse than the pain experienced after a hysterectomy (7–10). Studies conducted in Africa have shown a relatively high incidence of inadequate pain control with up to 32% of patients being unsatisfied with their analgesia after caesarean section (39–41).

There are numerous factors associated with inadequate postoperative pain control after a caesarean section. Inadequate analgesic prescription and/or administration due to concern about side effects to the mother or foetus remains an important factor (10,42). The combination of underestimation of the severity of pain by healthcare workers, with inadequate use of multi-modal analgesia, is frequently encountered (7). The availability of conflicting guidelines and use of generalised instead of patient-specific analgesic approaches, are also contributing factors (11).

1.3 Management of postoperative pain

1.3.1 Multimodal analgesia

No single analgesic agent can provide satisfactory postoperative pain management and thus a multimodal approach, which encompasses various agents blocking the pain pathway at different points, is considered the gold standard technique. This requires the combination of systemic analgesics with both central and peripheral regional nerve blockade (28). This will ensure that the minimum dose for each agent can be used, thus decreasing side effects and promoting early recovery after caesarean section (ERAC) (43). An ideal analgesic plan will have maximal effect in pain reduction with minimal side effects to the mother and infant (44). Emphasis should be placed on making tailored analgesic plans for individual patients and including their preferences as this has shown to improve pain control and reduce side effects (11). An acute pain service also helps to identify those patients who have breakthrough pain that requires further intervention.

1.3.2 Neuraxial anaesthesia

Neuraxial anaesthesia with a local anaesthetic agent is regarded internationally as the preferred anaesthetic technique for most uncomplicated caesarean sections. It provides high quality intra-operative analgesia and anaesthesia while reducing the risks associated with general anaesthesia (13–15,43). The Procedure Specific Postoperative Pain Management (PROSPECT) Working Group of the European Society of Regional Anaesthesia and Pain Therapy, makes evidence-based recommendations for postoperative analgesia in elective caesarean sections. They recommend an approach that comprises of a combination of a neuraxial anaesthetic with a long-acting opioid additive, intra-operative use of paracetamol and dexamethasone, with scheduled postoperative dosing of non-opioid agents such as paracetamol and non-steroidal anti-inflammatory drugs (NSAIDs), and judicious use of opioids for breakthrough pain (13).

1.3.3 Intrathecal opioids

Intrathecal opioids are commonly added to the neuraxial anaesthetic to prolong its analgesic effects (45). A long-acting hydrophilic opioid such as preservative free morphine is regarded as the gold standard additive to provide analgesia for up to 24-hours in the postoperative period (13). Despite its efficacy, it is also associated with many cardiovascular, respiratory, and metabolic side effects such as hypotension, delayed respiratory depression, nausea and vomiting, pruritis and fatigue (46,47).

For this reason, many guidelines recommend that patients receiving intrathecal morphine should have careful postoperative monitoring and vigilant nursing care (47). A short acting, lipophilic opioid such as fentanyl, is less likely to cause delayed postoperative cardiovascular or respiratory complications and requires less intensive postoperative monitoring (47,48). Fentanyl is more widely used in resource constrained environments, such as South African public hospitals (39,49). However, the short acting quality is unfortunately also a major limitation as fentanyl provides relatively limited analgesia in the postoperative period (48).

Importantly, the PROSPECT guidelines recommend that if intrathecal morphine is omitted, then additional regional local anaesthetic techniques should be utilised for lower abdominal analgesia (13). This is also supported by the Society for Obstetric Anesthesia and Perinatology Consensus Statement and Recommendations for Enhanced Recovery After Cesarean (43). Peripheral abdominal nerve blocks are encouraged as part of the multimodal strategy and have their greatest benefit when intrathecal morphine is not used.

1.4 Peripheral abdominal nerve blocks

1.4.1 Clinical importance

A variety of peripheral nerve block techniques have been developed for abdominal surgical procedures (30). Initially performed as landmark guided techniques, they are now mostly performed with ultrasound guidance. This greatly improves the ease of performance and reduces the risk of complications (30). These blocks involve deposition of local anaesthetic into fascial planes where thoraco-abdominal nerves run along their course from the spinal cord to their terminal nerve endings. This results in blockade of somatic pain stimuli to the spinal cord (16). These techniques cannot be used as a sole anaesthetic or analgesic technique for abdominal procedures as they have limited visceral blockade, and their somatic blockade can be incomplete due to variable spread of local anaesthetic in fascial planes (50).

Despite their limitations, peripheral nerve block techniques have become increasingly important in achieving the goals of early recovery after surgery. They offer significant reductions in pain scores and postoperative opioid consumption, making them useful adjuncts for postoperative pain management (50). Their opioid-sparing effects can reduce nausea, vomiting, pruritis, and respiratory depression. They can improve postoperative analgesia leading to earlier mobilisation, earlier resumption of oral intake, less opioid use and dependence, and earlier discharge from hospital (43). The greatest evidence for these blocks in caesarean sections, is when intrathecal morphine is omitted from the spinal anaesthetic due to opioid intolerance or contraindications for its use (13).

Similarly, they are also of benefit when other analgesic agents, such as NSAIDs, are contraindicated. Furthermore, they may be valuable when general anaesthesia is required and the usual benefits of a neuraxial technique are lost (16,43). They are also beneficial as rescue blocks for breakthrough pain postoperatively (30). They may also be utilised in patients who have risk factors for developing chronic pain syndromes.

1.4.2 Techniques

1.4.2.1 Transversus abdominis plane (TAP) block

The TAP block was the original fascial plane block utilised for post caesarean section analgesia. The block was first described by Rafi in 2001 as a landmark-based technique that targeted deposition of local anaesthetic into the potential space between the transversus abdominis and the internal oblique muscles of the abdominal wall (51). It is now more commonly performed under ultrasound guidance with greater efficacy and three approaches have been described, namely the subcostal approach, lateral approach, and posterior approach (52). The posterior approach is the most beneficial for caesarean section analgesia (53,54). A TAP block provides somatic analgesia by blocking anterior abdominal wall nerves, however, it lacks visceral analgesic effects (16,55). Several studies, including meta-analyses, have shown that TAP blocks can reduce opioid consumption, opioid-related side effects and improve pain scores after caesarean sections (56–60). Studies have shown the greatest benefit exists in the absence of intrathecal morphine (60).

1.4.2.2 Ilioinguinal & Iliohypogastric (II-IH) block

Ilioinguinal and Iliohypogastric nerves are branches of the L1 spinal nerve that enter the abdomen just above the anterior superior iliac spine (ASIS). These nerves supply sensory innervation to the inguinal and suprapubic dermatomes, thus making this block ideal for a Pfannenstiel incision (16,30). Like the TAP block, local anaesthetic is injected between the internal oblique and transversus abdominis muscles. It can be performed as a landmark or ultrasound-guided technique, with the injection made two centimetres medial and superior to the ASIS (16). A study by Bell et al (61) found reduced opioid consumption after 24 hours but no difference in pain scores or opioid-related side effects with II-IH blocks, after caesarean section. Sakali et al (62) found reduced opioid consumption and pain scores using II-IH blocks in patients receiving a general anaesthetic for a caesarean section.

1.4.2.3 Continuous wound infusion (CWI)

CWI is a technique whereby a wound catheter is placed between the rectus fascia and the skin. It is placed by the surgeon before closure of the skin. It is connected to a pump which delivers a constant infusion of local anaesthetic to the area. The analgesic effects are local and not dermatomal (16). Disadvantages of the technique include catheter migration, local infection, and risk of local anaesthetic systemic toxicity with prolonged infusions. A study by Lavand'homme et al (63) showed reduced opioid consumption and pain scores with a CWI technique whereas studies by Reinikainen et al (64) and Kainu et al (65) showed no differences in pain scores and opioid consumption. There are no systematic reviews to validate these studies.

1.4.2.4 Quadratus lumborum (QL) block

The QL block described by Blanco in 2007 is an ultrasound-guided variant of the initial landmark posterior TAP block. There are four described variants that differ slightly in the position that local anaesthetic is injected relative to the QL muscle. The ventral rami of the spinal nerves pass over the anterior aspect of the QL muscle thus it is potentially a more reliable block of thoracoabdominal nerves due to blockade of the nerves at a more proximal point. There is also thought to be paravertebral spread, via the endothoracic fascia, which may result in additional visceral analgesia (66). Several studies have shown significant reductions in opioid consumption and improved pain scores in the first 24-hours postoperatively when compared to placebos (67,68).

1.4.2.5 Erector spinae plane (ESP) block

The ESP block, described by Forero in 2016, is a new fascial plane technique that is thought to block dorsal and ventral rami of spinal nerves. The proposed mechanism is by diffusion of local anaesthetic into the paravertebral space, from the site of deposition under the erector spinae muscles, thus offering somatic and potentially visceral analgesia (18,69,70). However, there remains controversy as to whether ventral rami and sympathetic fibre blockade is achieved reliably with the ESP (71). Originally used for thoracic procedures, several studies have reported opioid-sparing effects and improved analgesia in upper and lower abdominal procedures (72–74). In contrast, other studies have shown it to have limited benefits compared to other techniques (75–77).

Its application in caesarean section analgesia is limited to a few case reports and small randomised controlled trials (RCTs). A case report showed successful use of the ESP block as a rescue analgesic, to reduce pain scores, after a spinal anaesthetic with intrathecal morphine (78). Two case reports have shown improved pain scores postoperatively with ESP use (79,80). A study by Dostbil et al (79) found reduced cumulative fentanyl consumption and prolonged time to first analgesic request in patients receiving ESP blocks compared to no block, after a caesarean section under spinal anaesthesia. A study by Hu et al (81) using ESP blocks before caesarean section under general anaesthesia, showed reduced intraoperative and postoperative opioid consumption and lower pain scores. Hamed et al (82) have shown lower postoperative tramadol consumption in the ESP group versus an intrathecal morphine (100mcg) group.

1.4.3 Comparison between block techniques

While many studies have shown favourable outcomes for these regional techniques when compared to placebo controls, there is greater heterogeneity in RCTs comparing techniques to one another. Additionally, there are few systematic reviews showing clear superiority between techniques for postoperative analgesia after caesarean section. A systematic review by Sultan et al (83) found the TAP block to be superior to wound infiltration, but equal to wound catheters in reducing opioid consumption and pain scores. Kiran et al (84) showed TAP blocks were superior to II-IH blocks in reducing opioid consumption and pain scores but a systematic review by Yetneberk et al (85) showed the techniques were equal. A study by Blanco et al (86) showed QL blocks were superior to TAP blocks in reducing pain scores and opioid consumption, yet a systematic review by El-Boghdadly et al (21) found the techniques to be equal. Studies by Priya et al (87) and Bakshi et al (88) showed ESP and QL blocks were equal for postoperative analgesia.

A study by Boules et al (19) showed longer block duration, lower opioid consumption and visual analogue scale (VAS) pain scores, but no difference in patient satisfaction between ESP and TAP blocks, after caesarean sections. Their study did not compare differences in opioid-related side effects between the blocks. Similarly, Malawat et al (20) also showed longer block duration, lower analgesic requirements and VAS pain scores but did not assess patient satisfaction nor opioid-related side effects between the blocks. A network meta-analysis comparing six peripheral nerve block techniques did not find the ESP block superior to the TAP block and recommended TAP blocks as the most comprehensive analgesic technique (89).

The ESP block has been compared to the TAP block in several other abdominal procedures with variable outcomes and great heterogeneity. Some studies have shown superiority with the ESP block (72,90) and others no difference between them (77,91,92). There is currently no consensus on the most superior peripheral nerve block technique for postoperative analgesia after caesarean section.

1.4.4 Peripheral abdominal nerve blocks in Southern Africa

Relatively few studies have been conducted in Southern African patient populations. A RCT by Marais et al (93), conducted in South Africa, showed TAP blocks can reduce opioid consumption after hysterectomies. No studies have compared ESP to TAP blocks in this patient population.

1.5 Summary

Patients undergoing caesarean sections still experience a high incidence of severe postoperative pain. International guidelines recommend a multimodal analgesic approach that achieves satisfactory analgesia with limited side effects to the mother and infant. Peripheral abdominal nerve blocks form an important component of this strategy. South African guidelines recommend the use of peripheral abdominal nerve blocks in the management of post-surgical abdominal pain. Specifically, TAP blocks are recommended for abdominal surgery including caesarean sections. The guidelines mention that newer blocks such as the ESP and QL block should also be considered, but good evidence for their superiority is lacking.

Multiple peripheral abdominal nerve block techniques are available that provide effective somatic analgesia. While there is no definitively superior technique, there is consensus that all techniques are better than using no block at all. Newer techniques such as the ESP and QL blocks may provide superior analgesia due to visceral analgesic effects, but the evidence for this is still lacking and requires further research. The aim of this study is to compare the postoperative analgesic efficacy of the ESP block to the TAP block after caesarean section under spinal anaesthesia, in a South African environment.

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Clinical Trial Registration Requirements

In an effort to promote transparency and accessibility and reduce the likelihood of authorial misconduct, all original research based on the results of completed or ongoing clinical trials must follow our Editorial Board's policies regarding clinical trial registration and accessibility. All original research submitted for consideration must adhere to the following guidelines:

- All trials must have been prospectively registered **before** the date on which patient enrollment began.
- All trials must be registered with a primary national trial registry such as the United States' [ClinicalTrials.gov](#) or the European Union's [EudraCT](#). If you do not know whether the registry to which you have submitted your work qualifies, a list of qualified national registries can be found on the [WHO International Clinical Trials Registry Platform](#).

- Your registration number and a link to your registration documents must be included in your manuscript. You must also explicitly state the date on which patient enrollment began.

Additional information regarding *RAPM*'s policies on clinical trials registration can be located [here](#). If you have any further questions, please contact the Editorial Office at info.rapm@bmj.com.

Proposals

RAPM editors will not preview works in advance of submission, but interested authors may send a short proposal for a prospective article to the Editor-in-Chief at brian.d.sites@dartmouth.edu for consideration.

Visual Abstracts and Infographics

Though not required, we encourage authors to supply a visual abstract or infographic in which the central findings of the paper are clearly articulated and represented. Examples of such images can be found [here](#) and [here](#). All images must contain the title of the paper, a list of authors, and a short summary of the paper's findings that consists of no more than two or three bullet points or sentences. If you are interested in providing a visual abstract or infographic, you can contact the journal's Editorial Production Assistant after your paper is accepted to express your interest. If your infographic is accepted, you will be asked to submit it as a separate manuscript.

For instructions on how to present your data, please see **[RAPM's Standardized Approach to Data Presentation](#)**.

Article Types

Original research

Original research should follow the basic structure of abstract, introduction, methods, results, discussion, references, with each section beginning on a new page.

- **Introduction** Clearly state the article's purpose. Give only pertinent references, and do not review the subject extensively. The final paragraph of the introduction should clearly state the hypothesis and primary outcome. Introductions should seldom exceed 1 page in length. Maximum length is 500 words.

- **Methods** Include information relevant to methods of research, including statements if needed regarding patient consent, IRB approval, and clinical trial registration. Describe clearly your selection of observational or experimental subjects. Identify methods, apparatus, and procedures in enough detail to allow others to reproduce the results. Include at least one paragraph to the tools of statistical analysis, including how sample size was determined. If the work required clinical trial registration, include the registry, registration number, date of registration, patient enrollment date, and a link to the trial's registration documents in the Methods section.
- **Results** Present your results in a logical sequence in text, tables, and illustrations. Emphasize or summarize only important observations.
- **Discussion** The first paragraph should summarize what your study showed. Emphasize new and important aspects of the study and conclusions that follow from them. Briefly discuss the limitations of your study. Summarize conclusions in a final paragraph.
- **Acknowledgments** Acknowledge only individuals who have made substantive contributions to the study (eg, statistical or editorial assistance), but who have not been included in the author list.

Supplementary and raw data can be placed online separately from the text, and we may request that you separate out some material into supplementary data files to make the main manuscript clearer for readers.

All original research submitted to *RAPM* must follow [EQUATOR Reporting Guidelines](#), as well as *RAPM*'s [RAPM's Standardized Approach to Data Presentation](#).

Additional Requirements for Clinical Trials

If your work is based on the results of a clinical trial, you must observe the following requirements:

- You must include the phrase “a randomized clinical trial” in the subtitle of your manuscript.
- You must explicitly state the date on which patient enrollment began and provide your trial registration number and a link to your registration documents in the manuscript.

- You must follow the CONSORT checklist and include the CONSORT flow diagram as a figure.

Word count: 1,500 to 3,000 words **Structured abstract:** up to 250 words **Introduction:** 500 words **Tables/figures:** up to 5 **References:** up to 30 Please include the key messages of your article after your abstract using the following headings. This section should be no more than 3-5 sentences and should be distinct from the abstract; be succinct, specific and accurate.

- **What is already known on this topic** – *summarise the state of scientific knowledge on this subject before you did your study and why this study needed to be done*
- **What this study adds** – *summarise what we now know as a result of this study that we did not know before*
- **How this study might affect research, practice or policy** – *summarise the implications of this study*

This will be published as a summary box after the abstract in the final published article.

RAPM: A Standardized Approach to Data Presentation

To facilitate readability, increase editorial efficiency, and allow comparisons between manuscripts, we have created the following document outlining in detail our recommended approach to standardization of data presentation for all manuscripts submitted to *Regional Anesthesia & Pain Medicine*.

The presentation of data in tables and figures should assist readers in the interpretation of research results. Keep data presentation as simple and clear as possible.¹ Avoid restating all findings in the text of the results section — instead, focus on the primary findings of interest. A comprehensive review can be found at *Reporting Statistical Information in Medical Journal Articles*.² Manuscripts should follow data reporting guidelines as outlined in the EQUATOR Network CONSORT Guidelines. Our guidelines are largely modeled after the recommendations from the *AMA Manual of Style, 10th Edition*.

General Principles

- Use past tense when referring to results in the text (e.g., “*We found a 30% reduction in the incidence of hospital readmission following...*”).
- The presentation of results should answer the research question and/or hypothesis.

- Avoid presenting redundant information in tables and figures (i.e., do not present the same results as both a table and figure).
- In general, results should first be reported unadjusted, with appropriate estimates of uncertainty.
- Present absolute rates and proportions prior to presenting comparative measures of association such as relative risk and odds ratios; for example:

When comparing patients having general anesthesia vs. nerve block, postoperative neurological sequelae occurred in 2 per 1000 vs. 1 per 1000, respectively; RR 2.0 (95% CI 1.8, 2.2).

- Do not use subjective qualifying terms for non-significant results such as “trend toward.”
- For all observational study designs (i.e., non-randomized studies), avoid using language that suggests causality. For instance, avoid describing results in the context of terms such as “effect” or “efficacy.” Instead, discuss relationships as “associations.”
- For all study designs, clearly state the primary and secondary outcomes (including adverse events measured).

Statistical Analyses Described in the Methods Section

- All analyses should follow the EQUATOR Reporting Guidelines and be consistent with the trial registration or study data plan.
- In general, the last paragraph of the Methods section should include an overview of the statistical methods employed. Specific mention should be made of the statistical tests that were used for the different types of data. It is not necessary to describe the measures of central tendency (e.g., mean and proportions) and dispersion used to summarize the study participants. For all primary and secondary analyses, authors should state the specific univariate statistical tests (e.g., independent sample t- test, chi-squared test) used to compare the groups. For example:

We used a t-test to compare means between the two groups for normally distributed, continuous data (e.g., blood pressure, opioid consumption, and comorbidity score), and a Mann-Whitney test to compare medians for skewed endpoints (e.g., length of stay, healthcare expenditures, and pain scores).

Sample Size Calculation

For all randomized trials, a sample size calculation is required. Achieving a sufficient sample size is critical to distinguish between a negative study (a study that finds no difference) versus a study that has unacceptable risk for a *Type II error* (i.e., incorrectly concluding that there is no difference between two groups when, in fact, one exists in the population). In general, for experimental study designs, sample size calculations should include the following:

- The chosen power of the study to detect a difference (1-beta), where beta is the probability of a Type II error (traditionally set at 0.20)
- The chosen critical alpha level (traditionally set at 0.05)
- Anticipated effect size of the intervention
- The measures of central tendency and dispersion in the two groups

Statistical Modeling

In randomized trials where factors are balanced at baseline, rarely are statistical models required. The exception to this is among randomized trials that collect repeated measures over time.

Observational study designs rely on statistical modeling to evaluate relationships while controlling for confounding factors or to create a model in order to predict an outcome. When data are either clustered within units (e.g., patients within hospitals) or repeated measures collected over time regression models (e.g., pain scores obtained daily for seven days after surgery), either mixed models or general estimating equations must be used. Clearly state the type of statistical model used, its structure, and the covariates included. For mixed models, identify the structure of the random effects (i.e., whether random intercepts or slopes were used) and the fixed effects included. When using generalized estimating equations, identify the correlation structure employed.

Multiple Comparisons

Use appropriate statistical methods to correct for multiple comparisons. Post-hoc comparisons should be clearly identified as comparisons that were conducted during data analysis.

Missing Data

In randomized trials, missing data as a result of loss to follow-up should be identified in the CONSORT diagram. In general, data from randomized controlled trials should be analyzed as intention to treat. For observational studies, identify missing data in descriptive tables and whether the participants were included in the analyses.

Format of Data Presentation

Authors should follow guidelines for data presentation as outlined in the EQUATOR network. When possible and regardless of study design, data should first be presented in unadjusted form consisting of rates or proportions with corresponding measures of uncertainty (e.g., standard error, 95% confidence intervals, etc.). Generally, distributions of continuous, normally distributed data should be summarized using the arithmetic mean and standard deviation (SD). Continuous data that are skewed (i.e., not normally distributed) should be summarized using the median and interquartile range (IQR). Alternatively, under certain circumstances, non- normally distributed data can be transformed to normal (e.g. log transformation) to facilitate parts of the analysis. Nominal and ordinal data (with few categories) should be summarized using both frequencies and relative percent in each category.

P-values

P-values should never be presented in isolation but should be accompanied by the measures in which they are comparing. For instance: “*Regional anesthesia compared to systemic opioids was associated with a reduction in mean length of stay by 1.2 days (95% CI 1.0 to 1.9; P = 0.03).*” P values should be presented with only two decimal points of precision. Values between 0.01 and 0.001 should be presented as “<0.01”. In regard to decimal point precision, the exception is p-values of less than 0.001, which should be presented as “<0.001”. For randomized trials, summary descriptive tables and text do *not* need to include p-values.

Table and Figures

Tables and Figures should accentuate and efficiently summarize the findings of the study. Use either 10- or 12-point font for tables. Each Table and Figure should be referenced in the text and included at the end of the manuscript. Each table and figure should contain enough information to be impactful without reading the manuscript.

Table Guidelines (see Table Example)

- Tables should be created with word processing software.
- Each data point must be in its own cell.
- Tables should always have at least two columns.
- For categorical data, include frequencies along with relative percent that add up across rows “n (%).”
- The denominator information should also be available in the columns (see below).
- Indents in table should be two spaces.
- Include p-values in a separate column with a footnote indicating which statistical tests were used.
- Superscripts in footnotes should be labeled as “a,b,c,d...” Do not use special symbols.
- Add a foot note if column data does not add up to 100% of data.

Figure Guidelines (see Figures 1 through 3)

Please see figure quality and file type requirement at <https://authors.bmj.com/writing-and-formatting/formatting-your-paper/>.

- Each Figure must contain title (and legend if needed). The title should fully describe what is shown in the figure. For instance, “30-day all-cause mortality following total shoulder replacement.”
- The figure legend should explain any symbols and abbreviations used.
- Do not include animations.
- Do not include pie charts.
- The y axis should not contain vertical text.
- Footnote superscripts should be indicated by “a,b,c,d...”

RAPM strongly encourages visual display of complex data. One of our favorite approaches is to create a Forest Plot (FIGURE 3) to display Odds Ratios, Relative Risks, or means.

Such a figure is immensely helpful when trying to display predictive models. When possible, and where appropriate, try to include both crude (unadjusted) and adjusted data

Medical Images and Video

When including media content, images and video should provide information that is not able to be communicated in text, tables, or figures. Supplemental media can be useful in the context of procedural and anatomical detail. Written patient permission must be obtained when involving human subjects and made available to the editorial office upon request.

References

1. Tufte, E. R. (2001). The visual display of quantitative information (2nd ed.). Cheshire, Conn.: Graphics Press.
2. Cummings P, Rivara FP. Reporting Statistical Information in Medical Journal Articles. *Arch Pediatr Adolesc Med*. 2003;157(4):321–324. doi:10.1001/archpedi.157.4.321

Manuscript

The Title of the Article Should Be Bold and Centered: Please Note the Use of Initial Caps

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Conflicts of Interest:

The authors declare no conflicts of interest [or state specific conflicts].

Funding:

The authors have no sources of funding to declare for this manuscript [or declare funding].

Running Head:

A Short Descriptive Title

ABSTRACT

Text here, using Structured or Unstructured Abstract format as appropriate, as described in Instructions for Authors.

INTRODUCTION**Subheadings May Be Used**

Text for the Introduction follows. Please use superscript numbers for cited references.

METHODS

Text for this section follows. Subheadings may be used as shown below.

Subheadings May Be Used

More text for this section follows.

RESULTS

Text for this section.

Table 1

Tables should be in Word format and placed in the main text where the table is first cited.

Tables 19 must be cited in the main text in numerical order. Please note that tables embedded as Excel files 20 within the manuscript are NOT accepted. Tables in Excel should be copied and pasted into the 21 manuscript Word file. Tables should be self-explanatory and the data they contain must not be 22 duplicated in the text or figures. Any tables submitted that are longer/larger than 2 pages will be 23 published as online only supplementary material.

Subheadings May Be Used

More text for this section follows.

DISCUSSION

Text for this section.

Conclusions

A short paragraph is often used to conclude the Discussion Section.

ACKNOWLEDGEMENTS

Text for acknowledgements.

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4. Ramirez MF, Ai D, Bauer M, et al. Innate immune function after breast, lung, and colorectal cancer surgery. *J Surg Res.* 2015;194:185–193

Section 3: Draft Article

A Randomised Controlled Trial Comparing Erector Spinae and Transversus Abdominis Plane Blocks for Postoperative Analgesia after Elective Caesarean Section

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Conflict of interest:

We declare that we have no financial or personal relationships which may have inappropriately influenced us in writing this paper.

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Running head:

Comparison of erector spinae plane and transversus abdominis plane blocks for caesarean section postoperative analgesia

Abstract

Background: Peripheral abdominal nerve blocks contribute to multimodal postoperative analgesia that enhances early recovery after caesarean sections. The transversus abdominis plane (TAP) block is an established technique that offers somatic abdominal analgesia. The erector spinae plane (ESP) block is a novel fascial plane block that may offer additional visceral analgesic effects. This study aimed to compare the postoperative analgesic efficacy of bilateral ultrasound-guided TAP blocks to ESP blocks in women undergoing caesarean sections under spinal anaesthesia.

Methods: Sixty-six ASA grade 1-3 (≥ 18 years) patients undergoing elective caesarean section under spinal anaesthesia were randomly allocated to receive either TAP blocks ($n = 33$) or ESP blocks at the T9 vertebral level ($n = 33$). The primary outcome measure was 24-hour cumulative morphine consumption. The secondary outcomes included the time taken to perform blocks, numeric rating scale (NRS) pain scores at 6- and 24-hours, effect of pain on activities of daily living (ADLs) and care for the newborn, time to first analgesic request, severity of opioid-related side effects, and patient satisfaction.

Results: There was no statistically significant difference in mean (SD) 24-hour cumulative morphine consumption between the ESP blocks and TAP blocks: 27 mg (14) vs 32 mg (15) ($p=0.185$). ESP blocks took longer to perform: 10.7 minutes (2.2) vs 9.0 minutes (2.5) ($p<0.01$). There were no significant differences in the other secondary outcomes.

Conclusion: The TAP block and ESP block were equally effective for postoperative analgesia after elective caesarean section under spinal anaesthesia. The ESP block did not demonstrate significant additional visceral analgesic effects.

Trial Registration: South African National Clinical Trial Registry (DOH-27-102022-5278), Pan African Clinical Trials Registry (PACTR202301645957324)

Introduction

Caesarean sections are associated with moderate to severe pain in the postoperative period.¹ Pain is a leading concern for patients undergoing caesarean sections and a major determinant of overall patient satisfaction.² Pain is associated with numerous adverse neuroendocrine effects that lead to several postoperative complications. It can reduce the ability of the mother to care for the infant and can lead to chronic pain, opioid abuse and dependence.^{3,4} The caesarean section carries a relatively high incidence of poorly controlled postoperative pain globally.^{3,5}

Obtaining maximal pain reduction with minimal side effects to the mother and infant can be achieved with a multimodal approach that includes peripheral abdominal nerve blocks as postoperative analgesic adjuncts.⁴ These blocks improve analgesia, are opioid-sparing, and can enhance early recovery after surgery.⁶ They are particularly beneficial when intrathecal morphine is omitted from a neuraxial technique, when other analgesic agents are contraindicated, and when general anaesthesia is used. Additionally, they may benefit patients at high risk for severe pain or chronic pain and may be used as a postoperative rescue analgesic technique.⁶⁻⁸

The transversus abdominis plane (TAP) block, described by Rafi in 2001, involves deposition of local anaesthetic between the transversus abdominis and the internal oblique muscles of the abdominal wall.⁹ It provides somatic analgesia of the abdominal wall but it lacks visceral analgesic effects.¹⁰ A meta-analysis by Champaneria *et al*¹¹ showed that TAP blocks reduce pain scores and opioid consumption thus several international guidelines recommend them as analgesic adjuncts after caesarean sections, especially when intrathecal morphine is omitted from a neuraxial technique.⁴

The erector spinae plane (ESP) block is a new fascial plane technique described by Forero in 2016, as a paravertebral technique that confers cranio-caudal spread of local anaesthetic from underneath the ESP muscles to the paravertebral space.¹² It offers somatic and potentially visceral analgesia.^{12,13} It has gained popularity due to its simplicity, safety, and ability to provide segmental analgesia for a variety of surgical procedures. Originally shown to have analgesic benefits for procedures of the thorax, there is now emerging evidence that low thoracic and lumbar ESP blocks have analgesic and opioid-sparing effects for abdominal surgery.^{8,12,14,15} Its application in caesarean section analgesia has recently been studied with limited evidence suggesting it may be superior to the TAP block.^{16,17}

There is a paucity of data on these regional techniques in low/middle-income countries (LMICs) such as South Africa. In addition, there is poor adherence to international guidelines that recommend using peripheral abdominal nerve blocks as analgesic adjuncts when intrathecal morphine is not used.⁴ To this end, this study hoped to improve analgesic practice by testing the hypothesis that the ESP block has additional visceral analgesic effects and offers superior analgesic efficacy to the TAP block. This study aimed to compare the postoperative analgesic efficacy of TAP blocks to ESP blocks in women undergoing caesarean section under spinal anaesthesia.

Methods

Ethical Approval

Ethical approval to conduct this study was obtained from the Human Research Ethics Committee (Medical) of the University of the Witwatersrand (M220512). The study was registered before commencement with the National Health Research Database (NHRD GP_202203_073), South African National Clinical Trials Register (SANCTR DOH-27-102022-5278) and Pan African Clinical Trials Registry (PACTR202301645957324). This study was conducted in accordance with the Declaration of Helsinki.¹⁸ Written informed consent was obtained from all participants.

Study design and participants

This study was a prospective, single-centre, randomised controlled trial with blinding at the level of outcome assessors. The study population included sixty-six American Society of Anesthesiologists (ASA) I-III obstetric patients (≥ 18 years) who were scheduled for elective caesarean section to be performed under spinal anaesthesia at the Rahima Moosa Mother and Child Hospital (RMMCH) in Johannesburg, South Africa. A consecutive convenience sampling technique was used, and the study took place from January until March 2023 until sample realisation was achieved. Exclusion criteria included patients that had a: BMI ≥ 35 kg/m²; pre-existing chronic pain syndrome; contraindication to spinal anaesthesia, local anaesthetic or opioids; physical or mental impairment which would prevent them from being able to use a patient-controlled analgesia (PCA) pump postoperatively; spinal anaesthetic that was converted to general anaesthesia.

Randomisation and blinding

Simple randomization was done with an allocation ratio of 1:1 using an online random number generator (GraphPad®, Dotmatics). Sealed, numbered, opaque envelopes were used sequentially to allocate patients. The sequence was generated by an independent assistant and envelopes were opened by the principal investigator (AE) once the patient was in the theatre. The outcome assessors collecting data for the primary and secondary outcomes remained blinded to the allocations throughout the study.

Block procedure

After informed consent was obtained for the procedure, an intravenous catheter was placed and a pulse oximeter, non-invasive blood pressure monitor (NIBP), and electrocardiogram (ECG) were applied to the patient as recommended by the American Society of Anaesthesia (ASA). The spinal anaesthetic was conducted by an independent anaesthetic practitioner. An aseptic technique was used to perform spinal anaesthesia in the sitting position with a 26-gauge pencil-point spinal needle (Ulifesa, Durban, RSA). After confirmation of clear cerebrospinal fluid, 9 mg of 0.5% hyperbaric bupivacaine with 10 mcg of fentanyl was introduced intrathecally. Patients were positioned supine with 15 degrees left lateral tilt and vital signs were observed at 1-minute intervals for the first 10 minutes and 2.5-minute intervals thereafter. An adequate spinal level was confirmed using an ice-cold pack. Surgery proceeded and after delivery of the foetus, a bolus of 2.5 IU of oxytocin was administered, followed by an infusion of 40 IU oxytocin in 1L Ringers Lactate at 125 ml/hr.

At the end of surgery, either a TAP block or ESP block was performed in theatre whilst the patient was being monitored as per ASA standards. All the TAP and ESP blocks were performed by AE to ensure standardisation of technique. The TAP blocks were performed in the supine position, using a curvilinear (2-5 MHz) ultrasound transducer (Mindray, Shenzhen,

China). The posterior approach was used with the probe placed midway between the subcostal margin and the iliac crest in the anterior axillary line. The fascial plane between the internal oblique muscle and the transversus abdominis muscle of the abdominal wall was visualised until it tapered toward the quadratus lumborum muscle. After sterilisation of the skin, a 21-gauge 110 mm echogenic needle (SonoTap, Pajunk, Geisingen, Germany) was introduced from anterior to posterior, and confirmation of correct needle placement was made by separation of the muscle layers with sterile saline hydro-dissection. After aspiration to exclude intravascular injection, 20 mLs of 0.25% bupivacaine with adrenaline was injected under vision. This procedure was then repeated on the other side of the abdomen.

The ESP blocks were performed with patients in the right lateral decubitus position. A curvilinear (2-5 MHz) ultrasound transducer (Mindray, Shenzhen, China) was placed longitudinally 2-3 cm lateral to the midline at the level of the ninth thoracic (T9) transverse process (TP). After sterilisation of the skin, a 21-gauge 110 mm echogenic block needle (SonoTap, Pajunk, Geisingen, Germany) was introduced in a cranio-caudal direction with an in-plane ultrasound approach. The needle was directed toward the TP and once on the TP, hydro-dissection with sterile saline was used to confirm adequate spread of fluid between the TP and erector spinae muscle group. After aspiration to exclude intravascular injection, 20 mLs of 0.25% bupivacaine with adrenaline was injected under vision. This procedure was then repeated on the other side of the spine.

Patients were transferred from the theatre to the recovery room where their vital signs were monitored and acute complications from the blocks were excluded. AE prescribed a standardised postoperative analgesic script consisting of paracetamol 1g 6-hourly, ibuprofen 400mg 8-hourly, and a rescue anti-emetic of metoclopramide 10 mg 8-hourly.

In the recovery room, all patients received a morphine patient-controlled analgesia (PCA) pump (CADD Solis®, Smiths Medical ASD, Inc, USA). The PCA pump, with morphine in a concentration of 1 mg/mL was set to allow a bolus dose of 1 mL (1 mg) with a 6-minute lockout and a maximum of 6 doses per hour. The PCA pump was locked with a pin code to prevent tampering. After discharge from the recovery room, patients were followed up by the blinded outcome assessors (members of the acute pain service at RMMCH) at 6-hours and 24-hours post block.

Outcome measures

The outcome assessors obtained cumulative 24-hour morphine consumption and time to first analgesic request, from the PCA pump electronic record. Numeric rating scale (NRS) pain scores were obtained using an 11-point scale (0 no pain, 10 worst pain) at rest and movement (cough), at time intervals 0-hours, 6-hours, and 24-hours after block completion. Outcome assessors conducted interviews at 24-hours where they assessed patients for opioid-related side effects (nausea, vomiting, drowsiness, itching), the effect of pain on activities of daily living (ADLs) and care of the newborn, and patient satisfaction. The data was captured on a data collection form by the outcome assessors and transferred onto an Excel™ spreadsheet (Microsoft Corp, Redmond, WA, USA) by AE for analysis.

Sample size calculation

The sample size was calculated in consultation with a biostatistician. Using the results from the study by Kamel *et al*,¹⁹ which used the same interventions as in the present study, a pooled standard deviation of 1.83, and a difference in means of 1.29 mg morphine use was calculated. These data were then used to calculate a Cohen's d value of 0.703, a large effect size. Assuming a power of 80%, a 5% significance level, and an effect size of 0.703, a minimum sample size of 33 participants per group was calculated.

Statistical analysis

Data was analysed using R v4.2.2 (R Core Team, 2022). Continuous numeric data such as age, weight, dose of morphine, duration of surgery and anaesthesia were summarised as mean (standard deviation, SD), while median (interquartile range, IQR) was used for scores (numerical rating scales) and discrete data (doses of drugs administered). Nominal categorical data were summarised using counts (percentage, %). For all analyses, a two-sided hypothesis was assessed, with statistical significance taken at $p < 0.05$. The primary outcome was analysed according to a pre-specified plan, with a Welch's t-test being used to compare 24-hour cumulative dose of morphine between the two groups. Consolidated Standards of Reporting Trials (CONSORT) guidelines were utilised in the study design, conduct of study, and presentation in line with EQUATOR network recommendations.²⁰

Results

Study participants

Participant selection and enrolment are summarised in the CONSORT flow diagram (Figure 1). Two participants in the ESP group could not tolerate the intravenous catheter attached to their PCA device and requested early removal of the PCA device. Thus, 33 participants per group were analysed for all primary and secondary outcomes. There were no statistically significant differences in demographic, anaesthetic, and surgical characteristics of the two intervention groups (Table 1). No complications were observed with either block.

Primary outcome

The mean (SD) 24-hour cumulative dose of morphine was 32 (15) mg in the TAP block group and 27 (14) mg in the ESP block group (Figure 2), with a mean difference of 4.8 mg (95% CI: -2.3 to 11.9). The difference between the two interventions was not statistically significant (t-value = 1.34, degrees of freedom = 63.79, $p = 0.185$).

Secondary outcomes

No statistically significant difference was found between the TAP block and ESP block groups for NRS pain scores at rest or with movement at 0, 6-, and 24- hours after block completion (Table 2). Additionally, there were no differences in the extent to which pain interfered with ADLs and care of the newborn (Table 2). Overall satisfaction with the analgesia provided was equally high in the groups (Table 2). There were no significant differences in the frequency or intensity of opioid-related side effects between the two groups (Table 3). There was no significant difference in median time (95 % CI) to first morphine PCA administration between the TAP group and the ESP group: 72 minutes (58 - 108) vs 84 minutes (65 - 122) ($p = 0.771$). The mean (SD) time taken to perform the ESP blocks was marginally longer than the TAP blocks: 10.7 minutes (2.2) vs 9.0 minutes (2.5) ($p < 0.01$).

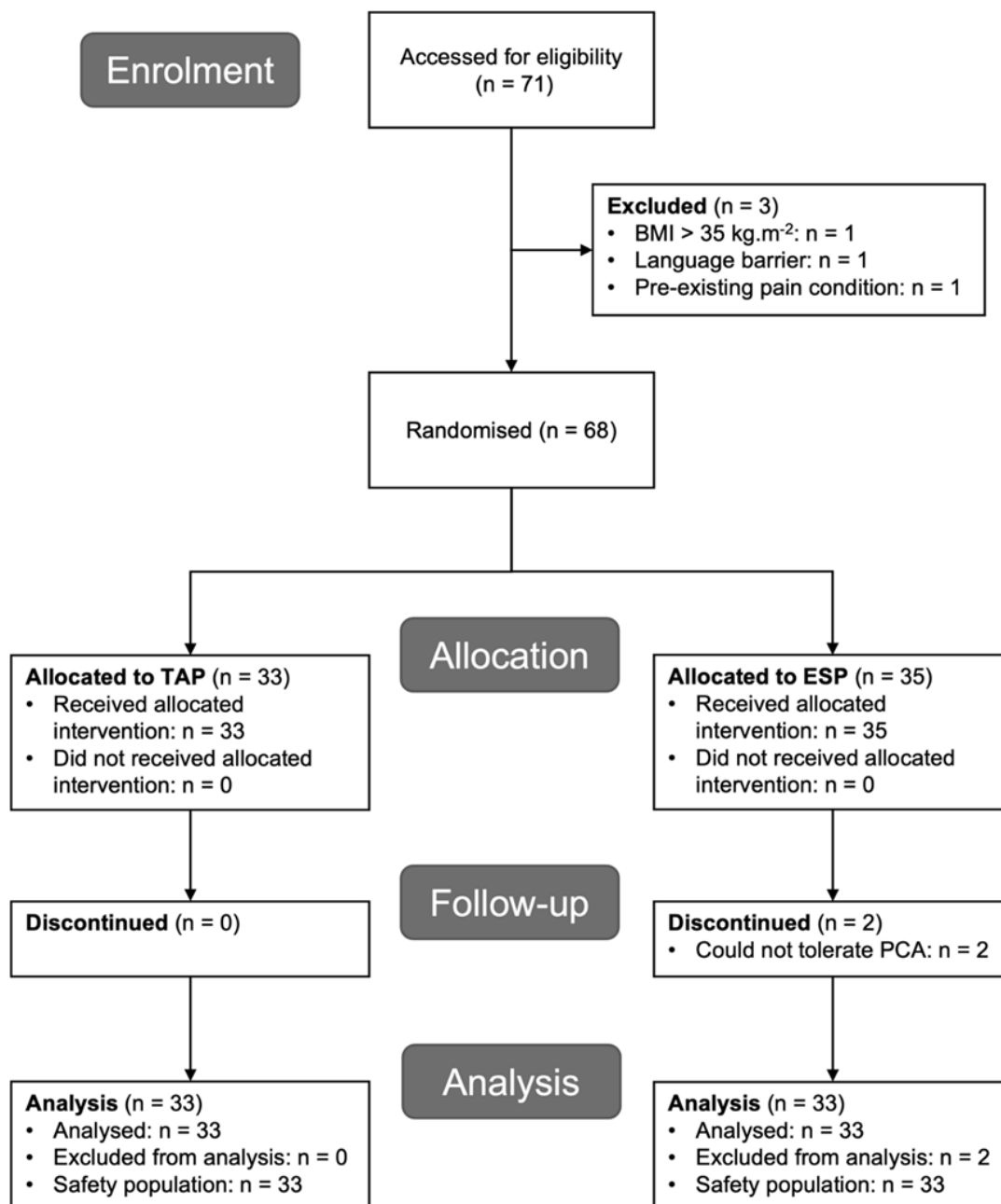


Figure 1. Consolidated Standards of Reporting Trials flow diagram of patient selection. TAP: transversus abdominis plane block, ESP: erector spinae plane block.

Table 1. Patient, anaesthetic, and surgical characteristics

	TAP Block	ESP Block	p-value ^{a,b}
Sample size, n	33	33	
Patient characteristics			
Mean age (SD) in years	30.5 (5.0)	31.1 (6.1)	0.60
Mean body mass index in kg/m ²	30.1 (3.2)	28.5 (4.5)	0.09
Parity, n (%)			> 0.9
Multiparity	31 (94)	31 (94)	
Primiparity	2 (6)	2 (6)	
Previous abdominopelvic surgery, n (%)	27 (82)	30 (91)	0.50
Surgical and anaesthetic characteristics			
Mean anaesthesia time (SD) in minutes	89 (21)	93 (17)	0.40
Mean regional block time (SD) in minutes	9.0 (2.5)	10.7 (2.2)	< 0.01
Mean surgical time (SD) in minutes	45 (19)	45 (18)	> 0.9
Type of skin incision, n (%)			0.60
Midline	1 (3.0)	3 (9.0)	
Pfannenstiel	32 (97)	30 (91)	
Adhesiolysis performed, n (%)	12 (36)	9 (27)	0.40
Parietal peritoneum closed, n (%)	22 (67)	17 (52)	0.20
Regional block complications			
None, n (%)	33 (100%)	33 (100%)	
Abbreviations: SD, Standard deviation; TAP, transversus abdominis plane; ESP, erector spinae plane			
a: p-value compares TAP to ESP			
b: Welch Two Sample t-test; Fisher's exact test; Pearson's Chi-squared test			

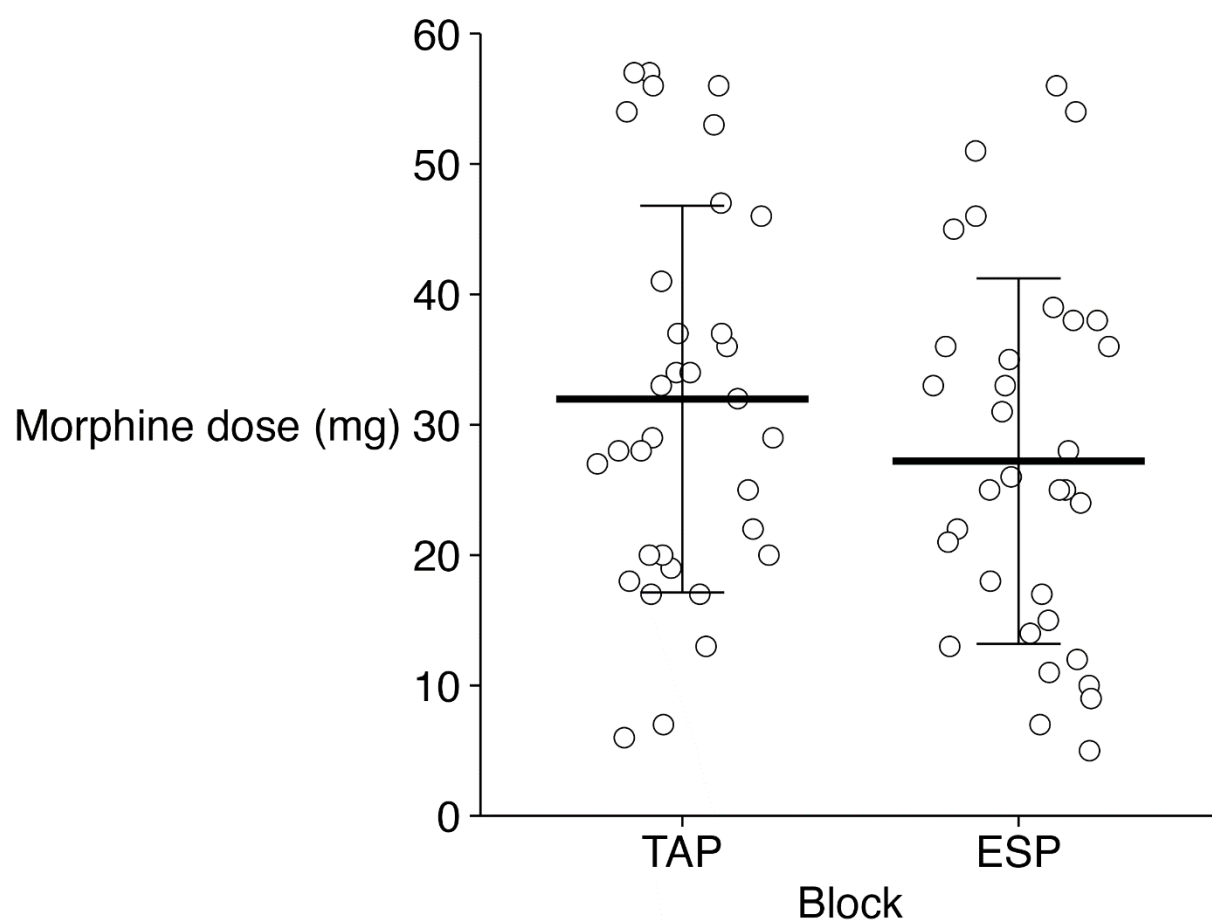


Figure 2. Mean (SD) 24-hour cumulative morphine dose administered via PCA device after caesarean section. TAP: transversus abdominis plane, ESP: erector spinae plane.

Table 2. Pain scores, pain interference and patient satisfaction

	TAP Block	ESP Block	p-value ^{a,b}
Sample size, n	33	33	
Median NRS pain score (IQR) at time 0-hour ^c			
At rest	0 (0-0)	0 (0-0)	0.5
With movement (cough)	0 (0-0)	0 (0-1)	0.5
Median NRS pain score (IQR) at time 6-hour ^c			
At rest	5 (3-8)	6 (5-6)	>0.9
With movement (cough)	6 (5-8)	7 (5-8)	0.6
Median NRS pain score (IQR) at time 24-hour ^c			
At rest	3 (2-4)	2 (1-4)	0.5
With movement (cough)	4 (2-7)	3 (2-5)	0.2
Median pain interference score (IQR) with ADL ^d			
Ability to move in bed	4 (2-5)	5 (3-7)	0.14
Ability to sleep	3 (1-4)	2 (0-4)	0.5
Ability to walk and stand	3 (2-6)	3 (1-5)	0.14
Ability to breastfeed	1 (0-3)	0 (0-3)	>0.9
Ability to care for infant	3 (1-5)	3 (0-4)	0.13
Median satisfaction score (IQR) at 24-hour ^e	9 (8-10)	9 (8-10)	0.8

Abbreviations: TAP, transversus abdominis plane; ESP, erector spinae plane; IQR, Interquartile range; NRS, Numeric rating scale; ADL, Activities of Daily living

a: p-value compares TAP to ESP

b: Wilcoxon sum rank test to compare NRS pain scores

c: 11-point numeric rating scale anchored at 0 (none) and 10 (severe)

d: 11-point numerical rating scale anchored at 0 (not at all) and 10 (extremely)

e: 11-point numerical rating scale anchored at 0 (not at all satisfied) and 10 (extremely satisfied)

Table 3. Opioid-related side effects

	TAP Block	ESP Block	p-value ^{a,b,c}
Sample size, n	33	33	
Nausea			
Incidence, n (%)	15 (45)	11 (33)	0.3
Median (IQR) severity score ^d	5 (2-6)	2 (1-4)	0.069
Vomiting			
Incidence, n (%)	10 (30)	10 (30)	>0.9
Median (IQR) severity score ^d	3 (1-8)	2 (2-4)	0.5
Drowsiness			
Incidence, n (%)	24 (73)	25 (76)	0.8
Median (IQR) severity score ^d	4 (2-6)	6 (3-7)	0.2
Itching			
Incidence, n (%)	11 (33)	5 (15)	0.085
Median (IQR) severity score ^d	5 (4-7)	5 (3-8)	>0.9

Abbreviations: SD, Standard deviation; TAP, transversus abdominis plane; ESP, erector spinae plane

a: p-value compares TAP to ESP

b: Pearson's Chi-squared test to compare incidence

c: Wilcoxon sum rank test to compare median severity score

d: 11-point numeric rating scale anchored at 0 (none) and 10 (severe)

Discussion

Peripheral abdominal nerve blocks remain important regional anaesthetic techniques for postoperative analgesia after caesarean sections as they have few complications and contribute to multimodal, opioid-sparing analgesia.⁸ The gold standard of spinal anaesthesia with intrathecal morphine has recently been challenged by a meta-analysis¹ which found that a combination of ilioinguinal-iliohypogastric nerve blocks with TAP blocks, in patients receiving intrathecal morphine, was superior to those receiving intrathecal morphine alone. These techniques are under-utilised in LMICs especially where other analgesic recommendations, such as those made by the Procedure Specific Postoperative Pain Management (PROSPECT) working group, are not fully adhered to.^{4,21}

This is the first study to compare the postoperative analgesic efficacy of TAP blocks to ESP blocks for caesarean sections, in a Southern African population. Importantly, aside from pain scores and opioid consumption, this study also looked for clinical significance in patient-centred outcomes, such as opioid-related side effects, the effect of pain on ADLs and patient satisfaction. This study found the two blocks to be equally effective for postoperative analgesia. There was no statistically significant difference in the primary outcome of 24-hour cumulative morphine consumption. In addition, the time to first analgesic request; severity of postoperative pain; incidence and severity of opioid-related side effects; effect of pain on ADLs and care of the newborn; and patient satisfaction between the two blocks were comparable. The ESP blocks took longer to perform, likely due to the lateral positioning required.

There is limited data comparing these blocks after caesarean sections. Two other studies in publication have shown superior analgesic efficacy with the ESP block compared to the TAP block, however, this study's findings are not consistent with those.^{16,17} Boules *et al*¹⁶ found a 25 mg lower median tramadol consumption with ESP blocks versus TAP blocks ($p<0.01$). They also found a mean visual analogue scale (VAS) pain score reduction of 0.32 in the ESP group versus the TAP group ($p<0.01$). Despite the difference in opioid consumption, there was no difference in patient satisfaction between the groups, which correlates with the findings of this study. Their study was different from this study on several grounds. Firstly, they utilised the lateral TAP block approach as opposed to the posterior approach used in this study. The posterior approach has been shown to be more effective.²² Secondly, they did not assess whether there was a difference in opioid-related side effects given the difference in opioid consumption.

The study conducted by Malawat *et al*¹⁷ also showed prolonged time to first analgesic request, lower total diclofenac consumption and lower VAS pain scores. In their study, a posterior TAP block was supplemented with rescue diclofenac boluses at a VAS score ≥ 40 mm, in contrast to this study, where patients could self-administer morphine for any quantity of pain. Additionally, they did not assess differences in patient satisfaction. Notably, a network meta-analysis by Wang *et al*²³ comparing six local anaesthetic techniques for caesarean section, did not find the ESP to be superior to the TAP block. They concluded that TAP blocks were overall the most effective local anaesthetic technique for postoperative analgesia.

The TAP block has been compared to the ESP block in several other abdominal procedures with variable outcomes. A study by Kamel *et al*¹⁹ found lower morphine consumption in patients receiving ESP compared to TAP blocks after total abdominal hysterectomy, but there was no difference in postoperative nausea and vomiting. A study conducted by Warner *et al*²⁴ in patients presenting for laparoscopic hysterectomies, showed no significant difference in pain scores, opioid consumption, or patient satisfaction between TAP and ESP blocks.

A study by Hassanin *et al*²⁵ on emergency laparotomies, showed lower cumulative fentanyl consumption in the ESP vs TAP group but the study did not assess differences in opioid-related side effects or patient satisfaction. A meta-analysis by Liheng *et al*²⁶ comparing ESP and TAP blocks for abdominal surgery found ESP blocks lowered opioid consumption and pain scores statistically, but did not reach clinically significant targets. Additionally, there were no differences in patient satisfaction.

There is conflicting evidence as to whether the ESP block has additional visceral analgesic effects that make it superior to somatic blocks, such as the TAP block. The extent and reliability of ventral and sympathetic rami blockade in the paravertebral space, based on clinical, cadaveric and MRI imaging studies, is still unclear.²⁷ While there is some evidence for potential visceral effects, there is a need to examine whether these statistically significant results equate to clinically significant outcomes. It could be argued that many of these results do not meet criteria for minimal clinically important differences (MCID) in pain scores and opioid consumption.^{27,28}

A recent systematic review found the TAP block was equivalent to the Quadratus Lumborum (QL) block for pain scores and opioid consumption after caesarean section.²⁹ Furthermore, Bakshi *et al*³⁰ showed ESP and QL blocks were equivalent for postoperative analgesia after caesarean sections. These studies suggest that none of these techniques are significantly superior to one another. Whilst more evidence is required to determine superiority between the two blocks, they can both be considered valuable tools in the regional nerve block armamentarium for caesarean section analgesia. This study emphasises that formulation of a customised analgesic strategy with the selective use of peripheral abdominal nerve blocks is of utmost importance, regardless of the technique used.

Several limitations exist in our study. This single-centre trial utilised convenience sampling over a short period of time that could have introduced selection bias and the results may not be extrapolated to all patient populations. We were not able to test the dermatomal adequacy of the block with sensory testing due to the effects of the neuraxial anaesthesia at the time of the blocks. Due to staff rotations in the pain service, different outcome assessors conducted follow up on the patients in the study which may have introduced interviewer bias. Although several Quality of Recovery (QoR) outcomes were evaluated, further studies utilising standardised tests such as QoR-15 to assist in determining clinically significant outcomes are recommended. The concept of the minimum clinically important difference (MCID) for pain outcomes needs to be carefully explored for caesarean sections to determine adequate sample size calculation and relevance of results.

Conclusion

This prospective, single-centre randomised controlled trial showed that bilateral, ultrasound-guided TAP blocks and ESP blocks are equally effective for postoperative analgesia after caesarean section performed under spinal anaesthesia. The ESP block did not show significant additional visceral analgesic effects.

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Contributors

AE: conceptualised the study design, wrote the study protocol, collected data, analysed the data, and wrote the first draft of the article.

JW: provided research support and assisted with study design, data analysis, data presentation and article drafting.

TK: provided research support and assisted with study design, data analysis, data presentation and article drafting.

PK: provided research support and assisted with study design, data analysis, data presentation.

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Section 4: Proposal

A randomised controlled trial comparing erector spinae and transversus abdominis plane blocks for postoperative analgesia after elective caesarean section

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4.1 Introduction

The caesarean section is one of the most frequently performed surgical procedures worldwide (1). Caesarean section rates in the South African public sector have nearly doubled from 2006 to 2017 (2). In Johannesburg public hospitals, monthly caesarean section rates may be as high as 41% (3). In the South African private sector, caesarean section rates exceed 75% (2).

Caesarean sections are associated with moderate to severe pain in the postoperative period and have been ranked in the top ten surgical procedures for pain severity (4–6). An increasing number of women are being exposed to a procedure with significant pain intensity which, if not adequately controlled, may lead to an increased burden of disease associated with higher healthcare costs (7).

Intraoperative and postoperative pain are leading concerns for patients undergoing caesarean section (8). Poorly controlled acute postoperative pain after caesarean section results in many adverse outcomes (9). Pain is associated with numerous neuroendocrine effects, which adversely affect the physiology of the central nervous, cardiovascular, respiratory, and gastrointestinal systems (10). Severe pain may reduce the ability of the mother to care for the infant and initiate breastfeeding successfully (9). It may also impair early ambulation, which increases the risk of thromboembolic events (4,11). In addition, it may contribute to hyperalgesia, chronic post-surgical pain (CPSP), post-traumatic stress disorder (PTSD), and postpartum depression (12,13). Studies have shown that up to 18% of patients develop chronic pain after caesarean section, with the severity of acute postoperative pain being a major predictor thereof (4,12). These patients are at further risk of developing chronic opioid use and dependence (1).

Caesarean section is associated with a high incidence of severe postoperative pain which is often not well controlled (9,14,15). A study conducted by Marcus et al. (16) described a higher incidence of poorly controlled pain in caesarean section patients when compared to patients undergoing hysterectomy and showed that caesarean section patients had a higher analgesic request. Studies conducted in Africa have shown poor pain control and patient satisfaction levels, with as many as 32% of patients being unsatisfied with their analgesia after caesarean section (17,18).

A study conducted at Chris Hani Baragwanath Academic Hospital found that 40% of caesarean section patients had inadequate pain control on discharge (19).

There are numerous factors associated with inadequate postoperative pain control after caesarean section. Inadequate analgesic prescription and/or administration due to concern

about side effects to the mother or foetus remains an important factor. The combination of underestimation of the severity of pain by healthcare workers with inadequate use of multi-modal analgesia is frequently encountered (11,16). The availability of conflicting guidelines as well as adopting a generalised instead of patient-specific analgesic approach, are also contributing factors (16).

International guidelines with evidence-based recommendations have been published to assist clinicians to provide a higher standard of care for caesarean section analgesia. The PROSPECT working group of the European Society of Regional Anaesthesia and Pain Therapy released an updated systematic review in 2021 for postoperative pain management for elective caesarean section performed under neuraxial anaesthesia (20). The guidelines encourage the use of multi-modal analgesia including neuraxial opioids and intravenous non-steroidal anti-inflammatory drugs (NSAID), paracetamol and dexamethasone. They recommend the use of other local anaesthetic techniques such as wound infiltration or fascial plane blocks as adjuncts for postoperative pain control. Guidelines from the American College of Obstetricians and Gynaecologists also support the use of fascial plane blocks to reduce postoperative opioid requirements (21).

When neuraxial anaesthesia is performed for caesarean section without intrathecal morphine, the recommendation is to use a fascial plane block to augment postoperative analgesia (20). These techniques are employed to minimise postoperative opioid use and its resultant side effects of nausea, vomiting, pruritis, urinary retention and dependence (20). Fascial plane blocks that have been studied for use after caesarean section include the Transversus Abdominis Plane (TAP) block, Quadratus Lumborum (QL) block and the Erector Spinae Plane (ESP) block (20).

Fascial plane blocks have become popular regional anaesthetic techniques over the last two decades due to their opioid-sparing effects and lower incidence of complications compared to neuraxial techniques and paravertebral blocks (22). They are also deemed easier to master as the target is a tissue plane rather than a focal space or individual nerve, and the widespread use of ultrasound has made confirmation of the correct location more accurate (23). They have also proven to be safe in patients on anti-coagulant therapy (24). Enhanced recovery after caesarean section (ERAC) protocols also support the use of fascial plane blocks as part of a multi-modal approach to managing post caesarean section pain (25).

The TAP block was the original fascial plane block utilised for post caesarean section analgesia. The block was first described by Rafi in 2001 as a landmark-based technique that

targeted deposition of local anaesthetic into the potential space between the transversus abdominis and the internal oblique muscles of the abdominal wall (26). A TAP block provides somatic analgesia by blocking anterior abdominal wall nerves however, it lacks visceral analgesic effects (27). Studies have shown that its use can reduce opioid consumption and improve pain scores (28–33). Other studies have shown TAP blocks to be no more efficacious than local anaesthetic wound infiltration (34,35).

The ESP block is a fascial plane technique developed in 2016 by Forero (36). Local anaesthetic is injected into the plane deep to the erector spinae muscle group of the back with the transverse process of the vertebral body being a bony target to guide correct needle placement. The theory for the mechanism of action of this block is that local anaesthetic can spread from its initial position into the paravertebral space via the superior costotransverse ligament. Once in the paravertebral space, local anaesthetic can block dorsal and ventral rami of spinal nerves, thus offering somatic and potentially visceral analgesia (22,37). The ESP block was initially described for relief of chronic thoracic wall pain, but its versatility lies in the fact that it is a paraspinal technique that can be performed at different vertebral levels resulting in analgesia for procedures at different anatomical locations. Thus, it has been studied in a variety of procedures of the chest, abdomen, and spine (38).

Studies have been conducted to compare the ESP block to the TAP block in abdominal procedures. Several studies have shown superiority of the ESP block over the TAP block in both upper and lower abdominal procedures (39,40). The theory that ESP blocks may offer visceral analgesia over and above the somatic analgesia given by TAP blocks makes it an important topic worth investigating further.

There is emerging evidence that the use of ESP blocks in caesarean sections to reduce pain scores and postoperative opioid consumption, is superior when compared to TAP blocks. A study conducted by Boules et al. (41) comparing ESP to TAP blocks for post caesarean section analgesia has shown reduced pain scores and postoperative tramadol consumption as well as longer analgesic duration of action. Similarly, Malawat et al. (42) have shown a prolonged time to first analgesic request and decreased postoperative analgesic consumption with ESP block compared to TAP block. Furthermore, a study by Hamed et al. (43) has shown decreased postoperative opioid consumption when ESP block was compared to intrathecal morphine.

An intrathecal hydrophilic opioid such as morphine is considered the gold standard additive to neuraxial anaesthesia for post caesarean section analgesia, but it is still not widely used as a

first line agent for caesarean sections in developing countries due to safety concerns (17). Various guidelines recommend prolonged monitoring up to 24 hours post administration of intrathecal morphine, which is challenging in resource limited settings (17,44). In public hospitals in Johannesburg, most patients receive a spinal anaesthetic with an intrathecal fentanyl additive as recommended by the South African Acute Pain Guidelines (45). Unfortunately, most of these patients are not supplemented with a fascial plane block as recommended.

There is a paucity of data among South African women as to the preference and superiority of analgesic techniques for caesarean section. Whilst some international studies may show superior outcomes for the ESP block over the TAP block, this may be different in South African women due to specific demographic characteristics and socio-economic or cultural differences (46).

4.2 Problem statement

Adequate postoperative analgesia is essential to avoid negative sequelae for the infant and mother after caesarean section. However, inadequate analgesia is still frequently reported in patients after caesarean section. With an increasing rate of caesarean sections in South Africa, inadequate analgesia could result in a large burden of morbidity with public health implications. There is a paucity of data among South African women as to the preference and superiority of postoperative analgesic techniques.

With respect to elective caesarean sections performed under neuraxial anaesthesia, various guidelines recommend the use of additional regional techniques such as fascial plane blocks as part of a multi-modal analgesic strategy. This is especially relevant when intrathecal morphine is not used in the spinal anaesthetic, which is the case in most caesarean sections performed in the South African public health sector. However, these techniques have not been widely incorporated into current South African analgesic practice.

While some international studies have shown that the ESP block may provide superior outcomes to the TAP block for post caesarean analgesia, no published data currently exists to support this in the South African setting. It is important that these techniques be examined to guide the development of clinical guidelines and improve current analgesic practice, patient satisfaction and enhanced recovery after caesarean section in an evidence-based manner.

4.3 Aim

The aim of this study is to compare the postoperative analgesic efficacy of the Erector Spinae Plane block to the Transversus Abdominis Plane block in women undergoing elective caesarean section under spinal anaesthesia at the Rahima Moosa Mother and Child Hospital (RMMCH).

4.4 Objectives

The primary objective of this study is:

- To determine and compare total 24-hour morphine consumption between the two groups of patients receiving ESP or TAP blocks during elective caesarean section performed under spinal anaesthesia.

The secondary objectives of this study are:

- To describe and compare the time taken until first morphine patient-controlled analgesic (PCA) use in both groups.
- To describe and compare the numeric rating scale pain scores at intervals 0-, 6-, and 24-hours in both groups.
- To describe and compare opioid-related side effects in both groups.
- To describe and compare patient satisfaction at 24-hours in both groups.
- To describe and compare the time taken to perform the blocks in both groups.

4.5 Research assumptions

The following definitions will be used in the study.

Adult: A person who is 18 years or older.

Elective caesarean section: A scheduled, non-emergent surgical procedure performed on a pregnant woman whereby the foetus is delivered from the abdomen of the mother through an abdominal incision for the benefit of the mother and/or foetus.

Acute pain: An unpleasant sensory and emotional experience associated with tissue damage.

Postoperative analgesia: Medication that is given before, during, or after the surgical procedure to alleviate pain that occurs from the tissue trauma induced by the surgical procedure.

Neuraxial anaesthesia: A procedure where a local anaesthetic agent is delivered into the subarachnoid space of the spinal column which contains cerebrospinal fluid via a needle inserted between the vertebrae of the spinal column

Surgical duration: From the start of skin incision until the application of wound dressing at the end of the procedure.

Anaesthetic duration: From time of first vital signs in theatre until time of first vital signs in the post-anaesthetic recovery area.

Fascial plane block: A type of regional anaesthetic block technique in which local anaesthetic is introduced into a tissue plane that contains multiple nerve branches.

Transversus Abdominis Plane block: A regional anaesthetic technique where a local anaesthetic agent is injected into the fascial plane between the internal oblique and transversus abdominis muscle layers of the abdominal wall.

Erector Spinae Plane block: A regional anaesthetic technique where a local anaesthetic agent is injected into the fascial plane between the transverse processes of vertebrae and the overlying erector spinae muscle group.

Intern: a qualified medical doctor having obtained their Bachelor of Medicine and Surgery in their undergraduate studies.

Medical officer: a qualified medical doctor working under supervision in the anaesthetic department who is not enrolled in a post graduate training program.

Registrar: a qualified medical doctor working under supervision in the anaesthetic department who is enrolled in a training post to become a specialist anaesthetist.

Outcome Assessor: A medical officer or registrar assigned to the acute pain service at Rahima Moosa Mother & Child Hospital. This individual will be responsible for following up all patients that receive ESP and TAP blocks, will collect data pertaining to pain scores, morphine consumption, and side effects.

4.6 Demarcation of study field

This study will be conducted at the Rahima Moosa Mother & Child Hospital (RMMCH) in Johannesburg. This hospital is a 351-bed central hospital providing obstetric, gynaecological, and paediatric healthcare. It is an academic teaching hospital affiliated to the Department of Anaesthesiology and Faculty of Health Sciences at the University of the Witwatersrand.

It has five theatres in the main theatre complex, which include dedicated theatres for both emergency and elective caesarean section deliveries.

Approximately 500 caesarean sections are performed at RMMCH per month. This study will be conducted in the elective caesarean section theatre, the theatre recovery area, and the postnatal maternity ward.

4.7 Ethical considerations

Approval to conduct this study will be obtained from the Human Research Ethics Committee (HREC) and the Post-Graduate Studies Committee of the University of the Witwatersrand (Faculty of Health Sciences).

Approval to conduct research will also be sought from RMMCH Research Committee (Appendix A). Consent will also be obtained from the departmental heads of Anaesthesia and Obstetrics at RMMCH (Appendix B). The study will also be registered on the National Health Research Database (NHRD) and the South African National Clinical Trials Register (SANCTR).

This study will be conducted in accordance with the Declaration of Helsinki (47) and the South African Guidelines for Good Clinical Practice (48). The principal investigator will also complete the required online ethics course as governed by the HREC of the university.

Patient consent to participate in this study will be sought at a preoperative visit in the antenatal ward the day before or day of the scheduled elective surgery. At this visit, patients will be approached by the primary investigator and offered the opportunity to be involved in the study.

A full explanation, as well as an information letter, will be provided in English (Appendix C) and written informed consent will be obtained (Appendix D) if the patient chooses to be involved in the study.

All data collected will be handled with utmost care to ensure confidentiality and anonymity are maintained. Patient identifying information will not be present on any of the data collection forms and a study number will be allocated to each participant.

A separate form that correlates the participant study number with their personal information will be kept separately and will only be available to the principal investigator and the outcome assessors.

All hard copy data, such as the consent forms and data collection sheets, will be stored for a period of six years in a locked cupboard or safe. All data that will be captured electronically using computer software will also be stored for six years on a secured device that has password protection.

To ensure the ESP and TAP blocks are conducted safely with appropriate technique, an independent experienced moderator will be requested to observe how the procedure is carried out by the principal investigator to ensure quality control and standardization.

4.8 Research Methodology

4.8.1 Research design

The study is a randomised controlled trial as patients booked for elective caesarean section, to be performed under spinal anaesthesia, will be randomly assigned to one of two intervention groups. The CONSORT guidelines' checklist for reporting on randomised controlled trials will be utilised to ensure standardization in reporting of the trial (Appendix E)

The trial will be performed at a single-centre and is considered prospective as data will be collected from participants that have undergone an intervention and are then followed-up to determine what outcomes occur and whether there is a significant difference between them.

A simple randomisation method will be used. Randomisation will be conducted using an online random number generator (GraphPad®). Two groups with equally allocated numbers for the intervention group and comparison group have been generated (Appendix F).

Patients assigned to receive the ESP block will be considered the experimental group and those assigned to receive the TAP block will be the comparison group. The aim is to determine if there is any difference in outcome between the two groups.

The study will be blinded at the level of the outcome assessors, who will not be aware of the treatment allocation (49). To ensure blinding of the outcome assessors, the block performed

will not be recorded on the data collection sheet used by the outcome assessors. The only exception to this will be if a complication is suspected in which case the outcome assessor may require this information to ensure no harm is done to the patient.

4.8.2 Study population

The study population will include all obstetric patients that are scheduled for elective caesarean section to be performed under spinal anaesthesia at RMMCH until sample realisation.

4.8.3 Study sample

4.8.3.1 Sample size

The sample size was calculated in consultation with a biostatistician. Using the results from the study by Kamel et al. (40), which used the same interventions that will be used in the present study, a pooled standard deviation of 1.83, and a difference in means of 1.29 mg morphine use was calculated. These data were then used to calculate a Cohen's d value of 0.703, a large effect size. Assuming a power of 80%, a 5% significance level, and an effect size of 0.703, a minimum sample size of 33 participants per group was calculated.

4.8.3.2 Sampling method

A consecutive convenience sampling technique will be used whereby all patients admitted and booked for elective caesarean section will be approached by the primary researcher, on days when the primary researcher is available to perform the blocks, to participate in the study.

4.8.3.3 Inclusion and exclusion criteria

Inclusion criteria:

- Elective caesarean section.
- Adult patients ≥ 18 years of age.
- ASA I - III.

Exclusion criteria

- Emergency Caesarean Section.
- BMI ≥ 35 (Taken at time of consent).
- Patients that do not give signed informed consent to participate.
- Contra-indication to spinal anaesthesia.
- Contra-indication to local anaesthetic agent or opioids.

- Patients requiring conversion from spinal anaesthesia to general anaesthesia at any stage during the caesarean section.
- Patients with any physical or mental impairment which prevents them from being able to use a patient-controlled analgesia (PCA) pump postoperatively.
- Patients with pre-existing chronic pain syndromes.

4.8.4 Data collection

Patient preparation:

The list of patients booked for elective caesarean section at RMMCH will be obtained from the obstetric department and the patients will be approached the day before their scheduled caesarean section. Informed consent will be obtained from willing participants. The explanation will include a discussion about their anaesthetic including both the spinal anaesthesia and the additional regional block to be performed.

They will be counselled about both the ESP and the TAP block and that they will be randomised to receive either one of them on the day of surgery.

They will also be informed that they will be given a morphine patient-controlled analgesia (PCA) device for postoperative analgesia. This is to be used for pain in addition to the standardised oral analgesics that will be prescribed and administered to them as per the obstetric departmental protocol. It will be explained to patients that they will be followed-up by a member of the acute pain service to check on their pain levels, ensure they are satisfied with their analgesia and monitor for side effects.

Patients that chose to be part of the study will also be counselled that if they are required to go for an emergency caesarean section or their elective caesarean section is performed at night when the principal investigator is not available, then they will be excluded from the study. A screening log will be kept recording all excluded patients and the reason for their exclusion.

Theatre procedure:

All participating patients will be treated in a uniform manner as per local hospital and departmental protocols. Once in theatre the patients will have monitors applied which include oxygen saturation, blood pressure and ECG as per American Society of Anaesthesia (ASA) standards. The patients will have intravenous lines inserted. The patients will receive a spinal anaesthetic that is administered in a standardised manner as per departmental protocols by one of the anaesthetic department's registrars, medical officers or by an intern with supervision. A separate consent will be obtained from this anaesthetist (Appendix G). The medication given

in the spinal will be a combination of 1.8 millilitres of bupivacaine 0.5% with dextrose (9 mg) and 0.2 millilitres of fentanyl 50 mcg/ml (10 mcg).

On the day of surgery, the participating patients will be randomised to receive either bilateral ultrasound-guided TAP blocks or bilateral ultrasound-guided ESP blocks. The ESP and TAP blocks will be performed by the principal investigator to ensure standardization of technique. Both the ESP and TAP blocks will be performed in theatre at the end of surgery whilst the patient is still under standard monitoring. Patients receiving TAP blocks will remain in the supine position and patients receiving ESP blocks will be turned into a right lateral decubitus position or sitting position for their blocks. These techniques have been used in previous studies with no resultant complications (30,41–43).

The standardised procedure for the administration of both the TAP blocks and ESP blocks will include:

- Monitoring of oxygen saturation, blood pressure, and ECG.
- An aseptic technique.
- Local anaesthetic dose: Each injection will consist of 20 millilitres of bupivacaine 0.25% (2.5mg/ml) with adrenaline prepared by dilution of 10 millilitres of bupivacaine 0.5% (5mg/ml) with adrenaline, with 10 millilitres of sterile water for injection. (Total volume of 40 millilitres, total dose of 100mg bupivacaine with adrenaline).
- Equipment:
 - Needle size: 100 mm Pajunk Sonotap Echogenic needle. (Sponsored consumable)
 - A fully ultrasound-guided technique will be used. (Departmental ultrasound)
- The blocks will be performed bilaterally.
- Hydro-dissection with normal saline will first be used to accurately find the correct tissue plane into which local anaesthetic must be deposited (51).
- Aspiration before injection to ensure no inadvertent intravascular injection

The following technique will be used for insertion of TAP blocks:

- Anatomic needle insertion point: Midway between the subcostal margin and the iliac crest in the anterior axillary line.
- Anatomic target: The fascial plane between the internal oblique muscle and the transversus abdominis muscle of the abdominal wall
- Confirmation of correct location: Separation of the fascial layers between the transversus abdominis and internal oblique muscles of the abdominal wall under ultrasound vision.

The following technique will be used for insertion of ESP blocks:

- Anatomic needle insertion point: A paramedian approach 1 - 2 centimetres lateral to the midline (spinous process) at the level of the ninth thoracic vertebral body
- Anatomic target: The fascial plane between the transverse process of the ninth thoracic vertebra and the erector spinae muscle group
- Confirmation of correct location: Separation of the fascial layers between the transverse process and the erector spinae muscle group under ultrasound vision.

The principal investigator will prescribe the oral analgesics and anti-emetics required postoperatively to ensure standardization. In the recovery area, all patients will receive a morphine PCA using a CADD Solis infusion pump (CADD consumables are sponsored). The PCA will consist of a 50-millilitre bag of normal saline with morphine in a concentration of 1mg/ml. The settings on the pump will be as follows:

- Bolus dose: One millilitre (1mg).
- Lockout: Six minutes.
- Maximum doses per hour: Six doses.

The use of an intravenous morphine PCA pump in place of the usually prescribed intramuscular pethidine will give a more reliable end point to assess opioid consumption. The morphine PCA has not been shown to be of any greater harm to mother or neonate than pethidine and in fact has been shown to result in less pain and less discontinuation of breast feeding than intramuscular pethidine (55).

Follow-up

Patients will be followed-up by a member of the acute pain service (outcome assessor) who will use the data collection sheet to record the required data. Patients will be assessed initially in the recovery area which will be considered time 0, and then again at 6- and 24- hours' time points postoperatively. They will ensure that the patient's pain and side effects are being adequately controlled and that the PCA is working correctly.

If a patient is found to have pain greater than three on the NRS pain score then the outcome assessor will determine if the patient has received all prescribed analgesics, is using their PCA appropriately and that the PCA is in working order. If additional analgesia is required, then the outcome assessor will contact the nurse in-charge of the patient's care and will arrange that the patient be given appropriate analgesia.

Data collection sheet

The data collection sheet section comprising of patient demographics and intraoperative events will be recorded by the principal investigator (Appendix H). Patient parameters such as parity, BMI, and number of previous caesarean sections are included as these factors may affect the amount of pain experienced by a patient. Intraoperative factors such as the type of surgical incision and adhesiolysis that may affect the degree of pain, are also included. Postoperative pain scores, opioid consumption, patient satisfaction and side effects will be recorded by the outcome assessor on follow up.

4.9 Data analysis

Data from the data collection sheets will be manually entered into a Microsoft Excel® spreadsheet or REDCap® tool and analysed with the assistance of a biostatistician.

The primary outcome (24-hour morphine consumption), secondary outcome (time to first morphine dose), and participant age will be summarised using means and standard deviations. All other variables are measured on ordinal scales and will be summarised using medians and interquartile ranges.

The primary outcome of 24-hour morphine consumption will be analysed using an unpaired t-test, assuming unequal variance (Welch's approximation will be used) and a two-sided hypothesis ($\alpha = 0.05$). The intention-to-treat population will be analysed. The secondary hypothesis of the time to the first dose of morphine will be analysed using the log-rank test. Exploratory analyses will also be performed on all outcome measured on the data collection form (see Appendix F). All these variables are measured on ordinal scales and will be analysed using ordinal logistic regression, with treatment group as the independent variable.

4.10 Significance of the study

The caesarean section is one of the most common surgical procedures performed in South Africa (1–3), and it is associated with a high degree of postoperative pain which has many potential negative sequelae for the mother and infant (1,4–6,9–13). There is a high incidence of poorly controlled postoperative pain both globally and in Africa (9,14,15,17–19).

Neuraxial anaesthesia, with a spinal anaesthetic, is recommended as the first choice for intraoperative analgesia; however, the postoperative analgesic effects are limited in duration

(20). Intrathecal morphine added to the spinal anaesthetic prolongs the analgesic effect but is associated with additional opioid-related side effects and requires more intensive postoperative monitoring (17,44). Current international guidelines recommend the use of additional local anaesthetic techniques such as fascial plane blocks as part of a multimodal analgesic strategy for postoperative pain, especially if intrathecal morphine is not used in the spinal anaesthetic (20,21).

The majority of South African women receive a spinal anaesthetic without intrathecal morphine; thus it is alarming that very few of them are receiving additional local anaesthetic blocks to reduce postoperative pain (52). The TAP block is an established fascial plane block that achieves somatic analgesia for caesarean sections (29–31,53). The ESP block is a newer technique, but evidence is emerging that it may offer additional visceral analgesic effects thus improving pain scores and reducing postoperative opioid consumption (22,37,41,42). This would make it a useful technique to be utilised to enhance early recovery after caesarean section and ensure high levels of patient satisfaction in South African women.

There is a paucity of data on these blocks in South African obstetric patients, similarly local guidelines and hospital protocols are also lacking (52). If we aim to achieve international practice standards, we need to have good evidence that these procedures will be of benefit to our patient population. Irrespective of the outcomes, the results of this study will further encourage evidenced-based practice of multimodal analgesia techniques in South African women undergoing caesarean section. It will also provide further evidence to assist with local guideline development.

4.11 Validity and reliability of the study

Validity refers to how accurately a study measures what it sets out to investigate and how well justified and truthful the conclusions are made. Reliability refers to how consistent and reproducible the research process is to obtain the generated results (54). Validity and reliability will be ensured by:

- Consultation with a biostatistician to generate a sample size and interpret the data collected.
- Employing an appropriate study design.
- Employing appropriate data collection methods.

- Employing appropriate inclusion and exclusion criteria to remove the effect of confounding variables.
- The principal investigator will carry out all the procedural components of the interventions being studied in a standardised manner to reduce inter-operator variability.
- Blocks will be performed under observation by a specialist anaesthetist initially to ensure correct technique and safety measures are being followed.
- Data collected by research assistants will be done with a standardised data collection tool.

4.12 Potential limitations of the study

- The sampling technique may introduce sampling selection bias as the sample recruited into the study from a single centre over a short period of time may not be fully representative of the population.
- The use of variable data collectors on follow-up may introduce some interobserver variability on data collection.
- The sample size has been calculated for the primary objective and therefore the study may not be adequately powered to detect small differences between intervention groups with respect to other secondary objectives.
- Although the hospital has a large geographic drainage area, the study is a single centre trial, and thus the results of the study may not be generalisable to other patient populations.

4.13 Project outline

Activity	Apr 2022	May 2022	June 2022	July 2022	Aug - Dec 2022	Jan 2023	Feb 2023	Mar 2023	Apr 2023	May 2023	Jun 2023	Jul 2023	Aug 2023
Postgraduate approval													
Ethics approval													
Data collection													
Data analysis													
Draft article													
Submission													

4.14 Financial plan

Description	Price per item	Amount of items	Total
Printing data collection forms	R 1 per page	600	R600
Printing research report	R 1 per page	800	R 800
Binding final research report	R 50	2	R 100
Consumables (Macaine)	R32	70	R2240
Consumables (Needles) - sponsored	0	70	0
PCA pumps (sponsored)	0	10	0
PCA spike sets/ disposables (sponsored)	0	70	0
Ultrasound machine (sponsored)	0	1	0
Total			R 3 740

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4.17 Appendices

4.17.1 Appendix A: Permission letter from RMMCH Research Committee



GAUTENG PROVINCE

HEALTH
REPUBLIC OF SOUTH AFRICA

Rahima Moosa Mother and Child Hospital
Enquiries: Adjunct Professor Ashraf Coovadia
Tel: 011 470 9284/9100
Email: Karen.Marshall@wits.ac.za

TITLE OF RESEARCH PROJECT:

'A RANDOMISED CONTROLLED TRIAL COMPARING ERECTOR SPINAE AND TRANSVERSUS ABDOMINIS PLANE BLOCKS FOR POSTOPERATIVE ANALGESIA AFTER ELECTIVE CAESAREAN SECTION'

NAME OF SUPERVISOR:

Dr Janine Wagner

NAME OF RESEARCHER:

Dr Aidan Eksteen
Department of Anaesthesiology
University of the Witwatersrand

NHRD REF NO: GP_202203_073

Dear Eksteen,

Permission is granted for you to conduct the research as indicated in the title above.

The terms under which this permission is granted is contained in the Researcher Declaration form that you have signed. Failure to comply with these conditions will result in the withdrawal of such permission.

It is crucial for you to inform the Research Coordinator, Karen Marshall of the actual start and end dates of your study. This could be done by e-mail.

Should the study commence more than 12 months after receipt of this approval letter you will have to go through the process of applying again.

You are strongly advised to keep a signed copy of the declaration form to ensure that the terms of this agreement are always complied with.

Yours sincerely,

MS. LESLEY ROSE

Acting Chief Executive Officer
Rahima Moosa Mother and Child Hospital

4.17.2 Appendix B: Permission from the Heads of Department



Permission to conduct research from the Head of Department: Anaesthesia

Dr A Eksteen
Department of Anaesthesiology
University of the Witwatersrand
eksteen.aidan@gmail.com
17/02/2022

The Head of Department: Anaesthesia, RMMCH

I am a registrar in the Department of Anaesthesiology. I am required to conduct a research report for my Master of Medicine in Anaesthesiology, through the University of Witwatersrand. I would hereby like to request your permission to conduct my study at Rahima Moosa Mother and Child Hospital in the department of Anaesthesia.

My study is titled "A comparison of Erector Spinae Plane block and Transversus Abdominis Plane block efficacy for postoperative analgesia after elective caesarean section". This is a randomised controlled trial, which seeks to determine which of the two regional anaesthetic techniques will provide superior postoperative analgesia and patient satisfaction after elective caesarean section performed under spinal anaesthetic.

I will invite patients booked for elective caesarean section to receive one of the two regional anaesthetic nerve blocks during their caesarean section. Written informed consent will be obtained from those that choose to take part. The patients will be given a morphine PCA pump postoperatively in replacement of their pethidine prescription, to supplement their oral analgesics. They will be followed-up by the acute pain service to determine how much analgesia they required in the ward and how much pain relief they obtained from these nerve blocks.

No additional cost will be incurred to the hospital as the consumables for the procedures have been sponsored by a medical equipment supplier. Postgraduate and ethics committee approval from the University of Witwatersrand will be obtained prior to the start of this study.

Yours sincerely,

Dr. Aidan Eksteen, MP0744581.

Permission ☒ granted / not granted by the HOD Anaesthesia

Name: Dr Thomas Kleyenstuber

Signed:

Date: 18 February 2022

Dear Dr

I have lo
Spinae Pl
elective c

I support

Regards
Dr A Wise
Acting HC
Obstetric
Rahima M

4.17.3 Appendix C: Participant information letter

Title of Research:	A randomised controlled trial comparing Erector Spinae and Transversus Abdominis Plane blocks for postoperative analgesia after elective caesarean section
Principal Researcher:	Dr Aidan Eksteen
Department:	University of the Witwatersrand - Anaesthesiology
Supervisors:	Dr J. Wagner, Dr T. Kleyenstuber

Introduction

My name is Aidan Eksteen and I am a doctor working in the anaesthetic department at Rahima Moosa Mother and Child Hospital. I am inviting you to take part in a clinical research study during your stay at this hospital. Please read through this information sheet and ask me any questions you have, to ensure that you understand it completely. If you would like to be part of this study, please sign the informed consent page. Thank you for taking the time to read this.

Purpose of the research

We are looking at how we can lessen the amount of pain women have after their caesarean sections so that they can be happier and more comfortable. Most patients will have a spinal injection in their back for pain relief during their caesarean section. Once the spinal starts to wear off, they start to feel pain from the operation. Patients usually receive pain killer tablets and injections after their operation to lessen this pain.

There is another type of injection used for pain relief called a ‘nerve block’, where a medication called local anaesthetic is injected around the nerves for pain. This helps to lessen the amount of pain you feel after your operation. We are looking at two of these injections to see which of them will help South African women the most.

The first injection is called the TAP block (Transversus Abdominus Plane block) which is an injection made in your lower stomach area and the second type is called an ESP block (Erector Spinae Plane block) which is made in your back muscles. These injections are done in theatre after your caesarean section to try and lessen your pain once your spinal wears off.

Voluntary participation & withdrawal

You can choose if you want to be part of this study. There will be no penalty or change in your level of care if you do not want to be part of it. Your treatment and the services you receive in theatre for your operation will also not be affected. You can change your mind at any time, even if you agree to participate now.

Participant selection

We are inviting all adult women who are coming to Rahima Moosa Mother and Child hospital theatres for an elective caesarean section under spinal anaesthetic to be part of the study.

Procedure

Once you arrive in theatre for your caesarean section you will be allocated to receive **either** the TAP injection **or** the ESP injection. This allocation will be random and neither you nor your doctor will be able to choose which injection you will get.

After the operation is finished you will be given either the TAP or ESP injection. The TAP injection will be made while you are lying flat, and the ESP injection will be made while lying on your side or sitting up. You shouldn't feel much pain as your spinal block will still be working.

Once your operation is finished, we will give you a machine called a PCA pump that you can use to give yourself a strong pain killer (morphine) in your drip when you are feeling pain. Another doctor will then come and see you in the ward after 6 hours and 24 hours to see how much pain you are feeling and if you are having any problems.

Risks and benefits

These injections are very safe and have been used for many women all around the world, but all treatments carry some risk. The injections can cause a small amount of bleeding like a bruise in the muscles which we can treat. You can have an allergic reaction to the medication injected which we can also treat.

There will be no direct benefits to you if you choose to be part of this study, but you could help us find out what is the best injection for women in the future.

Confidentiality

The personal information that we collect from this study will be kept safe and will not be shared. Only the researchers will have access to it. Any information we collect will be given a study number instead of using your name. No one except the researchers will know you were part of the study.

Contact Details

If you would like more information about this study at any time, or to report any problems or worries you have while being part of this study, please contact the principal researcher Dr Aidan Eksteen on the telephone numbers 011 470-9005 / 084 909 6177 , or by email on 0602611n@students.wits.ac.za. The contact number for the supervisors of this study are Dr J. Wagner on (082) 933 7194 or drjaninewagner@gmail.com and Dr T. Kleyenstuber on (082) 062 2516 or kleyenstuber@hotmail.com

Human Research Ethics Committee

This research has been approved by the Human Research Ethics Committee of the University of the Witwatersrand in Johannesburg. A principal function of this committee is to protect the rights and dignity of all human subjects who volunteer to participate in any research project, as well as to ensure the integrity of the research.

If you have any worried about the way this study is being run, please contact the Chairperson of this Committee, Professor Clement Penny, who may be contacted on telephone number 011 717 2301, or by e-mail on clement.penny@wits.ac.za.

The telephone numbers for the Committee secretariat are 011 717 2700/1234/2656 and their e-mail addresses are mapula.ramail@wits.ac.za, rhulani.mkansi@wits.ac.za and zanele.ndlovu@wits.ac.za.

4.17.4 Appendix D: Participant Informed Consent

Title of Research: A randomised controlled trial comparing Erector Spinae and Transversus Abdominis Plane blocks for postoperative analgesia after elective caesarean section

Participant:

I have been given a participant information letter explaining the nature and processes of this study which I have read or has been read to me, in the language I best understand. I have had the opportunity to ask questions and am satisfied with the answers given. I understand why this study is being conducted and how it will affect me. I voluntarily agree to participate in this research study.

Name of participant: _____ Signature
of participant: _____ Date:
_____ (DD/MM/YYYY)

Statement by the researcher/person taking consent

I have supplied the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the research being done. I confirm that the participant was given an opportunity to ask questions about the study. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

Name: _____
Signature: _____
Date: _____

Witness:

I have witnessed the accurate reading of the consent form by or to the participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness: _____
Signature of witness: _____
Date: _____ (DD/MM/YYYY)

4.17.5 Appendix E: CONSORT Checklist



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	6
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	7
	6b	Any changes to trial outcomes after the trial commenced, with reasons	7
Sample size	7a	How sample size was determined	7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	7
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	8
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	8
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	9
Recruitment	13b	For each group, losses and exclusions after randomisation, together with reasons	9
	14a	Dates defining the periods of recruitment and follow-up	9
Baseline data	14b	Why the trial ended or was stopped	9
	15	A table showing baseline demographic and clinical characteristics for each group	9
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	9
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	9
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	9
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	9
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	9
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	10
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	11
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	12
Other information			
Registration	23	Registration number and name of trial registry	13
Protocol	24	Where the full trial protocol can be accessed, if available	13
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	14

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

4.17.6 Appendix F: Randomisation chart

Group A = TAP block Group B = ESP block

Subject #	Group Assigned
1	A
2	A
3	B
4	A
5	B
6	B
7	B
8	B
9	B
10	A
11	A
12	A
13	A
14	A
15	B
16	B
17	B
18	A
19	A
20	B
21	B
22	A
23	A
24	B
25	A
26	A
27	A
28	B
29	A
30	B
31	B
32	B
33	B

Subject #	Group Assigned
34	B
35	A
36	A
37	B
38	B
39	A
40	B
41	B
42	B
43	A
44	A
45	B
46	B
47	A
48	A
49	A
50	A
51	A
52	B
53	B
54	B
55	A
56	A
57	A
58	B
59	B
60	B
61	A
62	A
63	B
64	A
65	A
66	B

4.17.7 Appendix G: Participant Anaesthetist Informed Consent

Title of Research: A randomised controlled trial comparing Erector Spinae and Transversus Abdominis Plane blocks for postoperative analgesia after elective caesarean section

Participant anaesthetist:

I have been given an information letter explaining the nature and processes of this study which I have read and understood. I have had the opportunity to ask questions and am satisfied with the answers given. I understand why this study is being conducted and how it will affect me and the patients under my care. I voluntarily agree to participate in this research study.

Name of participant anaesthetist: _____

Signature of participant anaesthetist: _____

Date: _____ (DD/MM/YYYY)

4.17.8 Appendix H: Data collection sheet

Participant study number			
Age			
Parity			
Previous abdominopelvic surgery			
Weight (kg)	Height (cm)	BMI	

INTRAOPERATIVE DATA

	Start	Stop	Total (minutes)
Anaesthetic duration			
Regional block time taken			
Surgical duration			
Type of skin incision			
Adhesiolysis performed	Yes	No	
Parietal peritoneum closed	Yes	No	
Complications			

POSTOPERATIVE DATA

P1. Total 24-hour Morphine consumption (mg) : _____

P2. Time to first Morphine PCA use (minutes) : _____

	Time 0	6 hours	24 hours
Rest			
Movement (cough)			

P3. Pain scores:

P.4 Postoperative analgesia received:

Drug	Dose	Doses received
Paracetamol		
Ibuprofen		

Other:		
--------	--	--

P5. Opioid related **side effects** in the last 24-hours:

Have you had any of the following side effects since your surgery?

a) Nausea

0	1	2	3	4	5	6	7	8	9	10
None					Severe					

b) Vomiting

0	1	2	3	4	5	6	7	8	9	10
None					Severe					

c) Drowsiness

0	1	2	3	4	5	6	7	8	9	10
None					Severe					

d) Itching

0	1	2	3	4	5	6	7	8	9	10
None					Severe					

P6. Patient **satisfaction** over the last 24-hours :

How satisfied are you with your pain control since your surgery?

0	1	2	3	4	5	6	7	8	9	10
Not at all					Extremely					
satisfied					satisfied					

P7. Would you have liked more pain treatment than you received?

Yes ☐ NO ☐

P8. How much did pain interfere with the following activities:

a) Doing activities in bed such as sitting up and changing position:

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

Not at all Extremely

b) Sleeping:

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

Not at all Extremely

c) Walking and standing:

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

Not at all Extremely

d) Breast feeding

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

Not at all Extremely

e) Caring for your baby:

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

Not at all Extremely

NRS Pain Scores: Time 0

On this scale, please indicate your current level of **pain at rest:**

0	1	2	3	4	5	6	7	8	9	10	
No pain											Worst pain

On this scale, please indicate your current level of **pain on movement:** (cough)

0	1	2	3	4	5	6	7	8	9	10	
No pain											Worst pain

NRS Pain Scores: Time 6 hour

On this scale, please indicate your current level of **pain at rest:**

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

No painWorst pain

On this scale, please indicate your current level of **pain on movement:** (cough)

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

No painWorst pain

NRS Pain Scores: Time 24 hour

On this scale, please indicate your current level of **pain at rest:**

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

No painWorst pain

On this scale, please indicate your current level of **pain on movement:** (cough)

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

No painWorst pain

Section 5 Annexures

5.1 Ethical Approval


UNIVERSITY OF THE
WITWATERSRAND
JOHANNESBURG

R14/49 Dr Aidan Eksteen

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M220512

NAME: Dr Aidan Eksteen
(Principal Investigator)
DEPARTMENT: Anaesthesiology
Rahima Moosa Mother & Child Hospital

PROJECT TITLE: *A randomised controlled trial comparing Erector Spinae and Transversus Abdominis Plane blocks for postoperative analgesia after elective caesarean section*

DATE CONSIDERED: 27/05/2022

DECISION: Approved unconditionally

CONDITIONS:

SUPERVISOR: Dr J. Wagner

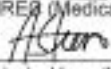
APPROVED BY: 
Dr CB Penny, Chairperson, HREC (Medical)

DATE OF APPROVAL: 23/08/2022

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on the Third Floor, Faculty of Health Sciences, Philip Tobias Building, 29 Princess of Wales Terrace, Parktown, 2193, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report.** The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in **May** and will therefore be due in the month of **May** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).


Principal Investigator Signature

26/08/2022
Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

5.2 Graduate studies approval

UNIVERSITY OF THE
WITWATERSRAND
JOHANNESBURG



Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172076

Reference: Mrs Sandra Benn
E-mail: sandra.benn@wits.ac.za

11 April 2022
Person No: 0602611N
PAG

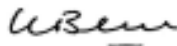
Dr AA Eksteen
14 Celia Avenue
Northcliff
2195
South Africa

Dear Dr Aidan Eksteen

Master of Medicine in Anaesthesia: Approval of Title

We have pleasure in advising that your proposal entitled *A randomised controlled trial comparing Erector Spinae and Transversus Abdominis Plane blocks for postoperative analgesia after elective caesarean section* has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely



Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

100
1922
2022

5.3 Turnitin Report

