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Ultrasound-assisted versus landmark-based spinal block performance in emergency caesarean delivery in obese patients at a central hospital

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg in partial fulfilment of the requirements for the degree of Master of Medicine in the branch of Anaesthesiology.

Johannesburg, 2020

Declaration

I, Bojan Korda, declare that this research report is my own unaided work. It is being submitted for the Degree of Master of Medicine in the branch of Anaesthesiology at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.



16 August 2021

Abstract

Background

An ultrasound-assisted spinal block technique for obstetric anaesthesia has not been studied in an African population or during emergency caesarean delivery (CD). The aim of the study was to assess the effect of preprocedural neuraxial ultrasound on the performance of spinal blockade in obese parturients undergoing spinal block for emergency CD in a central hospital in Johannesburg, South Africa.

Methods

A two-armed, prospective comparative contextual study design was used. Adult women booked for emergency CD under spinal block had preprocedural ultrasound performed before being randomised to either a landmark-based group (LMG) or an ultrasound-assisted group (USG). The USG had identified landmarks marked to assist the anaesthetist. The primary end-points were first-pass success rate, difficult spinal block rate, procedure time, number of needle punctures and needle passes. Secondary end-points include the intervertebral spaces attempted, the predicted ultrasound distance and actual needle depth.

Results

Thirty-six participants were recruited between January and February 2020. The USG was associated with a shorter procedure time (48s versus 97s, $p<0.05$) and fewer needle passes (3 versus 5.5, $p<0.05$). The LMG had a greater percentage of blocks performed at higher intervertebral spaces (L1/2 or L2/3) compared to the USG (66.7% versus 11.1%, $p<0.05$). The predicted ultrasound distance correlated well with the actual needle depth ($r = 0.86$, 95% CI 0.65 – 0.95) with a mean difference of 10 mm (range 0 – 25 mm).

Conclusion

Preprocedural ultrasound was associated with a statistically significant improvement in some technical measures of spinal block performance when used for emergency CD in an African population.

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Abbreviations

AD	Actual depth
ASA	American Society of Anesthesiologists
BCE	Before the Common Era
BMI	Body mass index
CHBAH	Chris Hani Baragwanath Academic Hospital
GA	General anaesthesia
IQR	Interquartile range
IVS	Intervertebral space
LMG	Landmark-based group
NA	Neuraxial anaesthesia
POCUS	Point-of-care ultrasound
SD	Standard deviation
UD	Ultrasound distance
UK	United Kingdom
USG	Ultrasound-guided group
WHO	World Health Organization

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 may differ from the author's guidelines of the British Journal of Anaesthesia, the journal to which it is intended to be submitted, in order to comply with the university's style guide. These differences include the referencing style and the numbering of figures, tables and pages.

Section 1: Review of the literature

1.1 Introduction

The provision of safe obstetric care is a global healthcare priority. The United Nations in 2015 ratified the Sustainable Development Goals (1), which guide governments to, among other priorities, set targets to reduce maternal mortality. In 2015, the World Health Organization (WHO) established the WHO Programme for Emergency and Essential Surgical Care (2), to promote a global surgery paradigm which supports safe anaesthesia and obstetric practice as the cornerstones for reducing maternal and child mortality. The Global Health Policy of the World Federation of Societies of Anaesthesiologists (3) maintains that safe anaesthesia is essential to provide safe surgery and that many maternal deaths could be avoided by improving anaesthetic capacity and provision in obstetric units. The South African government's National Development Plan 2030 (4) makes specific mention of reducing maternal mortality and providing improved access to obstetric and anaesthetic services. Over the past few decades, there has been a paradigm shift towards neuraxial anaesthesia over general anaesthesia as the standard for caesarean delivery, based on a perceived improved safety profile (5). Despite this, a study in 2019 revealed that potentially unnecessary general anaesthetics are administered in the obstetric population, as high as 6.4% (6), compared to the benchmark of less than 5% set by the Royal College of Anaesthesiologists (7). Preprocedural neuraxial ultrasound in obese parturients with difficult spinal anatomy is thought to be one way this could be reduced (8).

In this literature review, the use of preprocedural ultrasound to assist with neuraxial anaesthesia in obstetrics will be explored. First, the evolution of the practice of obstetric anaesthesia will be discussed, with a focus on the shift from general to neuraxial anaesthesia as the technique of choice during caesarean delivery. Next, the neuraxial anaesthetic techniques in obstetric anaesthesia will be explored. The evidence regarding the prediction of difficult neuraxial blocks will be detailed, with specific emphasis on the contribution of obesity and spinal abnormalities. The use of point-of-care ultrasound (POCUS) in anaesthesia in general, and obstetric anaesthesia specifically, will be highlighted. Finally, the

evidence around the use of neuraxial ultrasound specifically to facilitate neuraxial anaesthesia in obstetric patients will be discussed.

1.2 Evolution of obstetric anaesthesia from general to neuraxial techniques

Caesarean delivery is one of the oldest described surgical procedures, and is mentioned in various religious texts and historical accounts dating back to the first millennium BCE (9). With the advent of modern surgical practice from the mid-nineteenth century onwards, general anaesthesia with inhalational agents became the standard to facilitate caesarean delivery (10). Although neuraxial anaesthetic techniques for obstetrics were described prior to the 1930s, it was not until Virginia Apgar's work in the mid-twentieth century first highlighted the potentially deleterious effects of general anaesthesia that neuraxial anaesthesia became more popular (10, 11). Subsequently, landmark studies such as the Report on Confidential Enquiries into Maternal Deaths in England and Wales 1982 – 1984 (12) found that the use of general anaesthesia, in particular, due to difficulties during airway management, was also responsible for many maternal deaths. Similar findings were identified in South Africa in one of the early Saving Mothers Reports (13). In the 1980 – 1990s, the risk ratio for mortality under a general anaesthetic in the obstetric patient was 2.3 as compared to a neuraxial anaesthetic (14).

The recognition of the risks associated with general anaesthesia in the obstetric population led to a decline in its use as the anaesthetic of choice for caesarean delivery. In the period 1979 – 1985 in the United States of America, only 55% of caesarean deliveries were performed under neuraxial anaesthesia, while in the period 1985 – 1990, this grew to 84% (14). This change in practice was associated with a drop in the number of anaesthetic-associated maternal deaths (15). In 2020, the standard of care for anaesthesia for caesarean delivery is a neuraxial anaesthetic, with general anaesthesia reserved for emergency cases that are time-critical or where a neuraxial technique is contraindicated (16-18). Despite the shift towards neuraxial anaesthesia, a 2019 retrospective analysis indicated that a significant proportion of the remaining general anaesthetics for caesarean delivery

could be avoidable, although the precise reasons for this have not yet been clarified (6).

1.3 Neuraxial anaesthesia in obstetrics

Neuraxial anaesthesia for caesarean delivery can be performed by any of a number of techniques including a spinal (subarachnoid) block, an epidural block, a combined spinal-epidural, a dural puncture epidural or a continuous spinal block. Usage patterns of the specific techniques vary internationally (19), but in South Africa, the predominant technique is a spinal block (20). Neuraxial anaesthesia for caesarean delivery offers several advantages. It avoids the risk of establishing a definitive airway in a patient who is high risk for complications of airway management (11). It is associated with limited foetal drug transfer and toxicity, facilitates maternal involvement with the delivery process and thus improves bonding with the newborn. Neuraxial anaesthesia also results in reduced maternal blood loss, reduced post-operative pain and faster return to ambulatory function (11).

Neuraxial anaesthesia for caesarean delivery is not free of risks, but the incidence of serious complications is very low. The 3rd National Audit Project (21) examined major complications resulting in permanent harm following neuraxial anaesthesia in the United Kingdom. It reported the incidence of permanent harm in obstetrics to be particularly low, especially for a spinal block. Complications identified included paraplegia, peripheral nerve injury, meningitis, cardiac arrest and death, but only four complications out of 320 000 neuraxial anaesthetics administered were found in the obstetric population, and the vast majority of parturients receive quality analgesia and anaesthesia without any adverse events (21). The 2013 – 2015 UK and Ireland Confidential Enquiries into Maternal Death and Morbidity (22) showed that neither of the two anaesthetic-associated deaths were due to neuraxial anaesthesia-associated complications. The Cardiac Arrest in Pregnancy Study (23) showed that neuraxial anaesthesia was the most common precipitant of cardiac arrest in pregnancy, but that none of these resulted in maternal death.

Maternal mortality statistics from the United Kingdom differ from those of South Africa, where maternal mortality is much higher. The 7th Saving Mothers report

(24) indicated that of the 87 anaesthetic-associated deaths in the 2014 – 2016 period, neuraxial anaesthesia was associated with 79.3%. There was still a large number of anaesthesia-associated deaths that were likely due to poor airway management, resulting in either respiratory failure or hypoxic brain injury. Most of these deaths occurred in district hospitals with inadequately trained and under-prepared anaesthesia staff. Unfortunately, the available report lacks the detail required to explore the circumstances surrounding the anaesthetic choices and subsequent deaths (24).

An important reason for the provision of general anaesthesia in obstetric patients presenting for caesarean delivery is the failure of neuraxial anaesthesia (25). This has been associated with a larger patient body mass index (BMI), a more advanced active phase of labour, an urgent need for delivery and a greater ASA physical status class (26). Neuraxial anaesthesia failure can occur for a number of reasons, but importantly failing to reach the appropriate space for drug delivery is seen as a modifiable factor associated with failure (27). When neuraxial anaesthesia fails, the high risks associated with a general anaesthetic mean that special preparation and equipment (for example advanced airway equipment) must be available in all operative obstetric units (18). This is more difficult in resource-constrained settings such as South Africa, particularly at district or regional hospitals. Furthermore, staff in these peripheral sites are less likely to be proficient in the use of such advanced equipment, due to decreased availability and familiarity, lower caseload, less clinical exposure and a lower level of training (28). The relative rarity of a general anaesthetic for obstetric patients means that many staff in district hospitals have de-skilled, resulting in an increased complication rate for general anaesthesia when performed after neuraxial anaesthetic failure (24).

The need to convert to general anaesthesia after neuraxial anaesthetic failure represents a potentially modifiable factor for anaesthetic-associated deaths. The following section will examine which factors are associated with an increased difficulty in performing neuraxial anaesthesia, and therefore an increased risk of an “unnecessary” risk of conversion to general anaesthesia.

1.4 Predictors of difficult spinal anaesthesia

The success rate of neuraxial anaesthetics is generally high. In a prospective study assessing predictors of neuraxial block success, the first skin puncture success rate for all types of neuraxial technique was 91.2% in an adult population (29). Comparison of the anatomy of parturients during and after pregnancy showed that pregnancy is associated with a smaller epidural space, a greater skin-epidural space distance, a narrower space between spinous processes and a steeper angle of the interspinal space (30), therefore neuraxial anaesthesia becomes more technically challenging. There is also an increased risk of entering a higher spinal interspace, such as L1/2 (31). The level of the terminal part of the spinal cord ranges from T12 to L3, so entry at the L1/2 spaces has a higher risk of spinal cord injury (32). In keeping with this, the first-pass success rate in obstetric anaesthesia was only 44.5%, although the majority of blocks were successful in three passes or less (33).

De Oliveira Filho et al. (29) analysed factors affecting first skin puncture success in 1 481 patients undergoing neuraxial anaesthesia. Three independent predictors were identified – easily identifiable spinal anatomical landmarks, adequate patient positioning and an experienced anaesthetic provider. Statistical regression analysis found that poor patient positioning was independently predicted if the patient had any of the following characteristics: obesity (BMI > 30 $kg.m^{-2}$); age > 65 years; abnormal spinal anatomy and a brevilineal biotype. Independent predictors of poorly palpable spinal landmarks were: BMI > 25 $kg.m^{-2}$; age > 40 years; abnormal spinal anatomy and the brevilineal biotype. Furthermore, the study identified poor spinal anatomy and an increased number of attempts as predictive for complications of neuraxial anaesthesia. In this study, a patient was defined as having the brevilineal biotype if “the xiphicostal angle was > 90°” (29).

Ellinas et al. (33) prospectively analysed 413 pregnant patients undergoing neuraxial anaesthesia. It was found that the number of passes with the spinal or epidural needle and the time required to perform the neuraxial technique were increased if the patient had poorly palpable landmarks and/or had poor back flexion. Importantly, although an increased BMI was not identified as an independent predictor of a difficult neuraxial anaesthetic, it was a predictor of

poorly palpable spinal landmarks and poor patient back flexion. It is important that this obstetric-specific data corroborated previous studies regarding predictors of difficulty in a broader population (33).

In their respective studies on predictors of difficult neuraxial anaesthesia, neither De Oliveira Filho et al. (29) nor Ellinas et al. (29) distinguished between spinal and epidural anaesthesia. Unfortunately, the introduction of hybrid techniques such as combined spinal-epidural, continuous spinal anaesthesia and dural puncture epidural anaesthesia limits generalisability. Sprung et al. (34) in 1999 found no association between procedure difficulty and the use of either a spinal or epidural technique in a study involving 595 neuraxial blocks. Although it is pragmatic when designing a study to group all neuraxial anaesthetics together, it may mean that some of the identified predictors of difficulty may only be relevant to a specific technique. The question of whether different neuraxial techniques have different predictors of difficulty remains unanswered in the obstetric population.

Both ease of palpation of landmarks and the ability to adequately flex the back are subjective measures. Instead, factors deemed to correlate positively with these independent variables can be used as surrogates. These include an increased BMI (33), spinal abnormalities, increased age and brevilineal biotype (29). Increased age (over 40 years) is less likely to be a factor in the parturient population. The term “brevilineal biotype” is not used in the obstetric literature and can therefore be abandoned. Only obesity and spinal abnormalities are therefore relevant to the obstetric population. The next two sections examine the relevance of obesity and spinal abnormalities to the South African context.

1.4.1 Obesity

The WHO defines weight categories according to the BMI and describes obesity as “abnormal or excessive fat accumulation that represents a risk to health” (35). Obesity is defined as a BMI of ≥ 30 kg.m^{-2}, while overweight is defined as a BMI 25.00 – 29.99 kg.m^{-2} (35). BMI is a crude measure of fat accumulation, as it does not factor in sex, age, body composition or ethnicity (36). Different populations vary in fat distribution, with central adiposity in patients with a normal BMI still a risk factor for obesity-related morbidity. Alternative measures include waist

circumference, waist-to-hip ratio (37) and mid-upper arm circumference (38) but these definitions have not been universally adopted or reported. Despite its limitations, BMI is still ubiquitously used as it is relatively easily measured, and is the most widely reported indicator of increased fat accumulation at a population level (35).

The definition of obstetric obesity is controversial, with no universally accepted definition (39). Uncertainty exists as to when to measure the BMI, as pregnancy in a normal weight woman is associated with a gestational weight gain of between 11.5 – 16 kg by term, mostly in the third trimester (39). Women with pre-gestational obesity tend to gain relatively less weight during pregnancy. It has been suggested that BMI be calculated at the first antenatal visit, and not recalculated thereafter (39).

The WHO statistical estimates for the mean BMI and the prevalence of overweight and obesity in women in 1985 and 2016 are shown in Table 1.1. This table shows the rise in mean BMI and prevalence of overweight and obese women both globally and in South Africa (40).

Table 1.1 – Estimates of BMI and weight categories in adult females (40)

	Mean BMI ($kg.m^{-2}$)		**Overweight prevalence (%)** BMI ≥ 25.00 $kg.m^{-2}$		**Obesity prevalence (%)** BMI ≥ 30.00 $kg.m^{-2}$	
Year	**1985**	**2016**	**1985**	**2016**	**1985**	**2016**
Global	22.7 (22.5 – 22.9)	24.6 (24.4 - 24.8)	26.0 (24.2 – 27.8)	39.2 (37.3 – 41.1)	7.8 (6.9 – 8.7)	15.1 (14.0 – 16.2)
African region*	21.3 (20.8 – 21.7)	24.1 (23.8 – 24.3)	19.6 (16.8 – 22.7)	38.8 (36.2 – 41.7)	5.0 (3.9 – 6.2)	15.3 (13.6 – 17.1)
South Africa	26.8 (25.6 – 27.9)	29.3 (28.7 – 30.0)	45.5 (38.8 – 52.2)	65.4 (59.8 – 70.6)	21.4 (16.0 – 27.5)	39.6 (33.8 – 45.5)

Ranges in ( ) indicate 95% confidence interval

**As defined by WHO*

The epidemiological data in Table 1.1 show that the South African prevalence of obese adult females exceeds the world and African regional average by more than a factor of two. These data are not separated by ethnicity or age category, making

generalisation to the obstetric population difficult. A study looking at obesity in the urban obstetric population in Johannesburg found an incidence of obesity is 44% in a sample that was 94% African (41). The 2016 census showed Africans constitute 80% of the population (42).

Obesity in pregnancy is associated with a number of adverse perinatal and maternal effects including an increased risk of requiring emergency caesarean delivery (39, 41, 43). In particular, obese parturients have been identified as being at higher mortality and morbidity risk during anaesthesia (44). Ideally, early identification of obese obstetric patients with anaesthetic consultation should occur, as it requires additional planning and equipment (for example long needles, ultrasound and extra-large equipment). The high risk associated with general anaesthesia in this sub-population makes neuraxial anaesthesia technique of choice during caesarean delivery. Parturient obesity is associated with a higher risk of airway complications, hypertensive cerebral haemorrhagic strokes, surgical site infections and venous thromboembolic disease during general anaesthesia as compared to neuraxial anaesthesia (6, 44). There is also a high risk for conversion to general anaesthesia due to failed neuraxial anaesthesia (45). Difficulties in patient positioning, difficulties in landmark identification, increased skin-target distance and longer surgical time make neuraxial anaesthesia more challenging (46). This group, therefore, represents a population that could derive benefit from a technique that reduces the risk of neuraxial anaesthetic failure.

1.4.2 Spinal abnormalities

Abnormal curvatures of the spine may occur in the sagittal plane as either a kyphosis (backwards curvature) or a lordosis (forward curvature). An abnormal curvature in the coronal plane is called a scoliosis, while a complex three-dimensional combination is termed a kyphoscoliosis. Axial deformity can also occur and is measured by degrees of rotation from the sagittal plane (47). These terms are not always clearly differentiated in the literature, and scoliosis is often used to describe any abnormal curvature. There is little contemporary epidemiological data on spinal abnormalities in the pregnant population. A study in Israel during the period of 1988 – 2009 reported only 98 of the 229 116 pregnancies had scoliosis as a co-morbidity (48). A study in India reported on

46 828 pregnancies between 1998 – 2009, finding only 22 women with spinal abnormalities. Of the 22 patients, there were 13 with idiopathic kyphoscoliosis, 7 with neuromuscular kyphoscoliosis and 2 were secondary to trauma (49). No studies regarding the epidemiology of adult spinal deformities in Africa were identified.

Spinal abnormalities can be asymptomatic or result in severe functional impairment (50). Restrictive lung disease and a difficult airway are recognised complications of significant kyphoscoliosis. These factors make a neuraxial anaesthetic technique desirable due to a decreased risk of adverse respiratory events, in the absence of contraindications to neuraxial anaesthesia such as pulmonary hypertension (51). However, spinal disease itself also makes neuraxial anaesthesia more difficult to perform with an increased likelihood of failure. A systematic review by Ko and Leffert (51) on neuraxial anaesthesia in parturients with scoliosis showed a higher incidence of block inadequacy, failed placement, multiple placement attempts, unintentional dural puncture and overall neuraxial anaesthetic failure. Surface anatomy is distorted, and palpation of spinous processes becomes unreliable. These difficulties were still encountered even if the patient had had corrective surgery. Scar tissue formation, bone grafts and spinous process removal are thought to contribute (51). Despite this, successful neuraxial anaesthesia has been described in numerous cases involving complex or rare spinal disease. These include cases as diverse as rigid spine syndrome (52), Charcot-Marie-Tooth Syndrome (53) and spondylocostal dysostosis (54). The clear advantage of a successful neuraxial anaesthetic highlights the need to identify strategies to improve success rates. Ultrasound-assistance in this population has been suggested as a modality to achieve this (51). However, given the rarity of spinal disease in the obstetric population, a prospective study regarding ultrasound use during neuraxial anaesthesia would be difficult to execute.

Both obesity and spinal abnormalities make neuraxial anaesthesia more difficult but are not absolute contraindications. These same factors make a general anaesthetic equally or higher risk than a successful neuraxial anaesthetic. Any technique or technology available that could improve the success of neuraxial

anaesthesia would offer clear advantages in reducing anaesthesia-associated maternal mortality and morbidity. POCUS will be examined as one such potential technique in the next section.

1.5 Point-of-care ultrasound

POCUS is “ultrasonography brought to the patient and performed by the provider in real time” (55). POCUS is “goal-directed” in that it is used to assess a finite number of organs in a specific set of ways to answer clinical questions relevant to the clinician performing it. It is generally relatively quick to perform and uses a small number of views. It has the advantages of immediate clinical correlation, repeatability and versatility. This has been made possible by improved portability through miniaturisation, improved image quality and decreased costs of the ultrasound devices (55), as well as a more widespread acceptance of POCUS as an extension of the bedside examination (56). Conversely, traditional sonography involves imaging specialists (radiologists and sonographers) who typically perform more comprehensive sonographic examinations of whole anatomical areas (55).

POCUS’s increasingly broad utility has revolutionised the way medicine is practiced, particularly in the acute care setting. Clinical scenarios that involve emergencies mandate decision-making in the absence of all or even the most desirable information or investigations. Subsequently, there has been a proliferation of scanning protocols addressing numerous clinical scenarios, including vascular access, hypoxaemia, hypotension and cardiac arrest to name a few (57). Many of the mainstream applications of POCUS are supported by evidence and have been incorporated into major guidelines, for example, the guidelines for placing central venous catheters (58).

1.5.1 POCUS in anaesthesiology

The perioperative uses of POCUS are numerous and include vascular access, transthoracic echocardiography, cricothyroid membrane localisation, regional anaesthesia, neuraxial anaesthesia and gastric volume assessment (56, 59). A major advantage of POCUS in the perioperative setting is that a single device can address multiple clinical problems (60). This is particularly useful in a resource-constrained setting, where acquisition and maintenance costs are significant

barriers to equipment availability (61). The 2018 South African Society of Anaesthesiologists Practice Guidelines (62) list an ultrasound device as being desirable for a district hospital and essential for regional, tertiary and central hospitals. They recommend their use for central venous access and suggest basic transthoracic echocardiography is an integral skill for the practicing anaesthetist (62). No specific mention is made of its use in neuraxial anaesthesia.

Perioperative POCUS has not been without criticism. Inappropriate or inadequate examination may lead to unnecessary delays, or increase expense without benefit (55). The incorporation of POCUS as part of the core anaesthetic skill set raises a number of critical issues: training of already qualified practitioners; conditions for the attainment and maintenance of competence; certification and accreditation oversight and availability and maintenance of ultrasound equipment being a few (60). The issue of POCUS competence and accreditation in anaesthesia, particularly for specialists who finished their training prior to widespread availability and knowledge of POCUS, has been raised in the literature (56, 59, 63).

1.5.2 POCUS in obstetric anaesthesia

Ultrasound has traditionally been used by obstetricians for point-of-care assessment of parturients, and only over the past two decades has POCUS gained traction for use by obstetric anaesthetists (8). The uses of POCUS in obstetric anaesthesia include vascular access guidance (central venous, peripheral venous and arterial); gastric volume assessment; airway management; and cardiac and pulmonary evaluation (8). However, the bulk of the obstetric-specific evidence relates to its use in facilitating neuraxial anaesthesia (8).

A 2013 United Kingdom national survey (64) of obstetric anaesthesia services showed 67.3% of respondents had access to an ultrasound device in the obstetric unit and 50.7% had a dedicated anaesthetic obstetric ultrasound device. Of those having access to an ultrasound device, only 22.2% used them to facilitate neuraxial anaesthesia, although this represented an increase from previous studies. The ultrasound was instead more commonly used for transverse abdominis plane blocks and obtaining vascular access (64). The 2020 Royal College of Anaesthetists obstetric anaesthesia service guidelines (65) recommend

the availability of an ultrasound device to facilitate neuraxial anaesthesia. No similar guidelines regarding minimum standards have been published by the Obstetric Anaesthesia Special Interest Society in South Africa. No literature describing availability of ultrasound in anaesthetic departments in South Africa could be identified.

1.6 Ultrasound-assisted neuraxial anaesthesia

Ultrasound-assistance during procedures is divided into static guidance and dynamic guidance. Static guidance involves preprocedural ultrasound to identify a structure of interest and mark the optimal site for instrumentation, as well as the depth and angle of entry. The procedure is then done separately. Static guidance is also sometimes termed “ultrasound-assisted”, “ultrasound-assistance”, “pre-procedural” or “pre-puncture”. Dynamic guidance involves the visualisation of the needle in real-time during instrumentation, allowing for adjustments as the instrument (often a needle) is advanced towards the target. It allows for correction of errors in trajectory but has limitations that include the potential loss of sterility and the requirement of greater dexterity in an often restricted area. Dynamic guidance is also termed real-time ultrasound guidance (55). This terminology is not strictly adhered to throughout the available literature. Dynamic guidance is the gold standard but is not always feasible. With regards to ultrasound-guided neuraxial anaesthesia, real-time guidance has been described but is restricted to a few centres with specialised or experimental equipment. The majority of the available literature instead pertains to ultrasound-assisted techniques (66).

The first documentation of ultrasound-assisted neuraxial anaesthesia was in 1980 by Cork et al. (67). Since the early 2000s, the evidence regarding ultrasound-assisted neuraxial anaesthesia has grown. Benefit has been demonstrated in a variety of anaesthesia-related clinical contexts, including paediatric anaesthesia, obstetric anaesthesia, geriatric anaesthesia, thoracic neuraxial anaesthesia and lumbar neuraxial anaesthesia (66). In obstetric anaesthesia, it has specifically been shown to facilitate anaesthesia for caesarean delivery and labour analgesia, during spinal block, combined spinal-epidural and epidural neuraxial techniques (68). A comprehensive meta-analysis of the utility of lumbar neuraxial ultrasound was published in 2016 by Perlas et al. (69). Thirty-one original studies were

analysed and included studies up to the year 2014. Another narrative review of broader applications of neuraxial ultrasound was published in 2018 (66). The evidence from the two publications as it relates to neuraxial anaesthesia is summarised below, with specific individual studies highlighted where relevant.

Ultrasound-assisted neuraxial anaesthesia allows for preprocedural identification of all the component structures between the skin and the neuraxial target, as well as adjacent structures such as the vertebral articular processes, transverse processes and erector spinae muscles (68). It allows determination of the appropriate intervertebral level and midline; the optimal point and angle for needle puncture and the depth of the target (68, 69).

Identification of the correct intervertebral space is essential. A study has shown that the standard palpation landmark-based technique misidentifies the level (70). An inappropriately high level of spinal needle puncture risks damage to the conus medullaris and permanent neurological fallout (11). Evidence exists that African individuals tend to have spinal cords that terminate at lower levels than in other populations, potentially increasing their risk of injury (31). A systematic review (69) identified multiple studies that consistently showed ultrasound-assisted methods for lumbar space identification perform better than landmark-based methods. In direct comparisons, palpation-based identification of landmarks was higher than ultrasound-based identification in 52 – 78% of cases. Compared to lumbar x-ray and magnetic resonance imaging, sonographically identified spaces were correct 71% and 76% of the time, and never erred by more than one interspace level. Palpation-based identification, in contrast, was accurate only 21% of the time as compared to lumbar x-rays and was wrong by more than a single interspace 27% of the time. Some of these studies were specifically done in parturients (69). Locks et al. (70) demonstrated benefit in level identification even in a non-obese parturient subgroup.

Preprocedural ultrasound has also been shown to accurately predict the needle depth required to reach the epidural and intrathecal spaces. The meta-analysis by Perlas et al. (69) showed that ultrasound predicted the actual needle depth to within 3 mm, with a range of between 1 – 13 mm. Ultrasound consistently

underestimated the depth, this was largely thought to be the result of the compressive effect of the ultrasound probe on the subcutaneous tissues (69).

Several scanning protocols have been developed to facilitate neuraxial anaesthesia. These include the transverse median approach (A), the paramedian sagittal oblique approach (B) and the longitudinal median approach (C), as shown in Figure 1.1 (68). The transverse median approach allows for accurate identification of the midline as well as the depth of spinal structures such as the dura mater. The angle of entry for a needle can also be identified according to how the probe is tilted to obtain the optimal image (71). The paramedian sagittal oblique approach has the advantage of the best acoustic window to identify deep vertebral and spinal structures and therefore allows accurate estimation of the depth of the subarachnoid and epidural spaces from the skin (72). The longitudinal median approach has very limited views of the deep structures within the vertebral canal due to acoustic shadowing from the spinous processes, only allowing for accurate identification of intervertebral level (68). Each protocol has advantages over the others and in practice more than one protocol is utilised according to the needs of the individual patient.

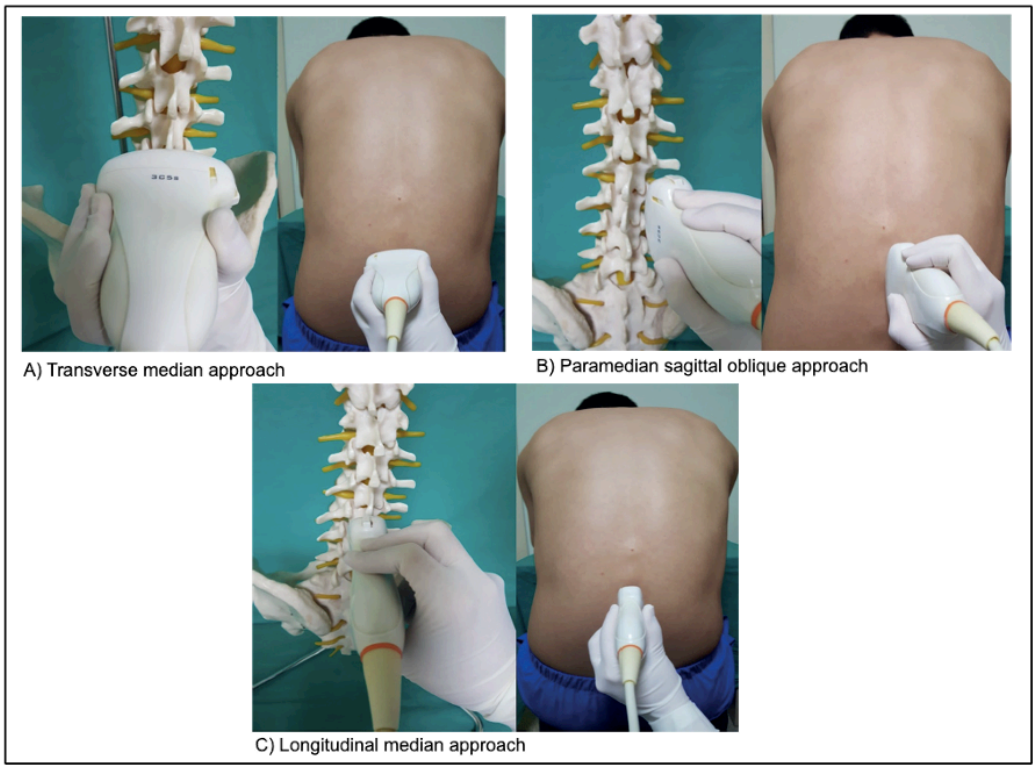


Figure 1.1 Probe positions for different ultrasound scanning protocols (68)

Next, the clinical data regarding ultrasound-assisted neuraxial anaesthesia will be explored, and its utility in the context of obstetric anaesthesia for obese parturients will be critically appraised.

Clinical utility of neuraxial ultrasound in obstetric anaesthesia

Chin (66) concluded in a narrative review that studies that found no or minimal benefit in lumbar neuraxial anaesthesia over the past decade have a number of problematic features. All the studies were performed on patients who had easily palpable spinal landmarks or had a normal BMI, and therefore no predictors of difficulty (73-76). Only two studies specifically examined spinal block administration as opposed to epidural or combined spinal-epidural anaesthesia (73, 75). Turkstra et al. (73) introduced potential bias by having experienced practitioners coaching trainee anaesthetists despite them being in the control arm of the study. Ansari et al. (75) only included experienced anaesthetists with no trainee involvement.

Conversely, studies have shown benefits to using preprocedural ultrasound. There are best demonstrated in studies involving parturients that are either obese (77, 78) or have poorly palpable spinal landmarks (79). The meta-analysis by Perlas et al. (69) showed level Ia evidence that preprocedural ultrasound-assistance resulted in a lower number of needle passes required for success. It also noted a reduction in the risk of failure with a risk ratio of 0.51 (95% CI 0.32 – 0.80) and a number needed to treat of 16 to prevent one failure. Given the rarity of severe complications of neuraxial anaesthesia, none of the studies analysed in the meta-analysis were powered to demonstrate a reduced risk of severe complications. However, the reduced number of skin punctures or passes and improved intervertebral space identification accuracy are likely to reduce the incidence of backache and spinal cord injury (69). As a result of this meta-analysis, as well as some subsequent studies, Chin et al. (66) have suggested that neuraxial anaesthetics in patients with risk factors for difficultly should all be performed under ultrasound-assistance. Sahin et al. (80) demonstrated in 2014 that in addition to reducing the number of attempts in obese parturients, preprocedural ultrasound also reduced the number of attempts in lean ones. In 2019, Li et al. (78) in an elective obese obstetric population demonstrated an improved first-pass

success rate, reduced number of needle passes, reduced procedure time and improved patient satisfaction in the ultrasound-assisted group (78). This same study specifically categorised a difficult spinal block as one requiring > 10 needle passes and showed a significant difference between the groups in this regard (78).

Chin et al. (81) in 2018 showed a benefit in first-pass success (63.8% versus 38.2%), need for additional needle punctures (19.0% versus 38.2%) and need for additional needle passes (34.3% versus 58.2%) in all parturients with an ultrasound-assisted as compared to landmark-based technique, even those with easily palpable spinal landmarks. In this study, the ultrasound was performed by anaesthetists experienced in neuraxial ultrasound, but the combined spinal-epidural anaesthetic was performed by trainee anaesthetists (81). This benefit may be clinically irrelevant for elective patients, but in an emergency where a delay is expected, for instance when the only available operating theatre is already occupied, there may be a role in sonographically assessing and marking the landmarks of the incoming patient in order to save time when the operating theatre does become available. Dhanger et al. (82) found improved technical success in obstetric patients regardless of the presence of poorly palpable landmarks or obesity. This may indicate that there is a role for preprocedural ultrasound in more patient groups than previously thought. The evidence in this area continues to evolve.

There are several disadvantages to using preprocedural neuraxial ultrasound. There is evidence that it increases the total procedural time, 8 ± 2 min versus 5 ± 1 min (77). Neuraxial ultrasound is also technically difficult due to the presence of small acoustic windows (68) and the relatively steep learning curve for the trainee, requiring in excess of 20 procedures before attaining competency (83). Finally, although ultrasounds are becoming increasingly available in anaesthetic obstetric units (64), they still represent an additional cost, the benefit of which may not align with the demands of a busy department, particularly in a resource-constrained setting.

The available data does leave some questions unanswered. No studies examining POCUS use in emergency caesarean delivery could be identified, the available obstetric literature focussing instead on elective cases. Though this is likely due to

ethical concerns in this vulnerable population, it does introduce potential bias and limits generalisability to all obstetric spinal anaesthetics. No studies assessing the utility of ultrasound-assistance during spinal anaesthesia in a predominantly African population were identified. Furthermore, ultrasound-assisted neuraxial anaesthesia for obstetric patients with spinal abnormalities is unlikely to gain a robust evidence base, given the low incidence of spinal pathology in obstetrics (49). Case reports of ultrasound-assisted neuraxial anaesthesia for caesarean delivery in women with spinal disease have been published, however, including parturients with spinal metastases (84) and achondroplasia (85).

The evidence shows that ultrasound-assisted spinal anaesthesia for caesarean delivery is likely to have some benefit in reducing procedural time and the number of attempts, while also reducing minor common complications such as back-pain and possibly reducing the risk of major complications such as neurological injury. This benefit is likely to be greatest in patients who are at high risk of having a difficult neuraxial procedure, such as obese parturients.

1.7 Summary

The provision of safe anaesthesia for caesarean delivery is a global healthcare priority. Although improvements in anaesthetic safety have been made over the last few decades, opportunity exists for further improvements by reducing the need for general anaesthesia. One potential avenue to explore is ultrasound-assistance prior to neuraxial anaesthesia, particularly if difficulty is anticipated. Ultrasound-assistance may reduce the need for conversion to general anaesthesia, which has significantly higher risk in this population. It could also reduce procedure time, as well as reduce complications associated with neuraxial anaesthesia. Neuraxial ultrasound has not been studied in the context of emergency caesarean deliveries, or in the South African environment or population.

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Section 2: Author's guidelines

BJA author guidelines

Manuscripts

For guidance, the requested size for articles is:

Clinical investigations: up to 3000 words and 30-40 references, 4-6 tables or figures.

Submissions which ignore this guidance on word count or number of figures/tables may be returned without being assessed. Authors wishing to submit manuscripts with figures/tables in excess of the recommended number should justify this in the submission letter.

For review articles and laboratory/clinical investigations it is possible to include supplementary data (such as additional references for a review, expanded tables of results or additional images for investigations) for on-line publication only. Authors should make clear in their submission letter which files are to be considered for on-line only publication.

Preparing your manuscript

The standard layout of a manuscript is:
• Title page
• Summary, including Keywords
• Introduction (not headed)
• Methods
• Results
• Discussion
• Details of authors contributions
• Acknowledgements
• Declaration of interests
• Funding
• List of references
• Tables (including legends to tables)
• Legends to illustrations
The pages should be numbered in the top right-hand corner, the title page being page one, etc. Start each section on a separate page.

Title page

A separate page which includes the *title* of the paper. Titles should provide a reasonable indication of the contents of the paper. This is important as some search engines use the title for searches.

Therefore, it is best to avoid enigmatic or vague titles such as 'An unusual cause of hypotension'. Titles in the form of a question, such as 'Is propofol epileptogenic?' may be acceptable.

The title page should include the name(s) and address(es) of all author(s). It should be made clear which address refers to which author. Details of the authors' qualifications and post (e.g., consultant, senior lecturer) are not required. An author's present address, if it differs from that at which the work was carried out, or special instructions concerning the address for correspondence, should be given as a footnote on the title page and referenced at the appropriate place in the author list by superscript numbers ([1][2][3] etc.) If the address to which proofs should be sent is not that of the first author, clear instructions should be given in a covering note, not on the title page.

All authors should follow the criteria for 'authorship' as determined by International Committee of Medical Journal Editors. For details, please refer to section on *British Journal of Anaesthesia* Policies.

A short running title containing not more than 50 characters (including spaces) should be included.

Summary (abstract)

The Summary (Abstract) will be printed at the beginning of the paper. It should be on a separate sheet, in structured format (Background; Methods; Results; and Conclusions) for all Clinical Investigations and Laboratory Investigations. For Reviews and Case Reports, the Abstract should not be structured.

The Abstract should give a succinct account of the study or contents, in up to 250 words. The Results section should contain data. It is important that the results and conclusion given in the Abstract are the same as in the whole article, as the Abstract may be used, as it stands, by abstracting journals. References are not included in this section.

Keywords

Three to five keywords should be included on the summary page under the heading Keywords. They should be in alphabetical order and must be classified according to MESH keywords. These can be found here. Please note that UK English spelling will be used for these. Please do not simply list words you think are key. For example, propofol should be listed as: anaesthetics i.v., propofol;

Introduction

The recommended structure for this section is;
• Background to the subject
• What is known / unknown about it
• What bit you are interested in / hypothesis

• Aim of your study

As a rule, the introduction to a paper should not require more than about 200 words and have a maximum of 1.5 pages double-spaced. The introduction should give a concise account of the background of the problem and the object of the investigation. It should state what is known of the problem to be studied at the time the study was started. Previous work should be quoted here but only if it has direct bearing on the present problem. For example, a description and evaluation of an analgesic infusion as part of an intravenous anaesthesia regimen need not include an exhaustive account of the previous literature addressing the problems of intravenous anaesthesia and the many studies of different analgesics, etc.

The final paragraph should clearly state the primary and, if applicable, secondary aims of the study.

If a preliminary account of the results has been given in a published abstract, it is customary to refer to this.

Methods

The Methods section should give a clear but concise description of the process of the study. Subjects covered in this should include:

• Ethics approval / licence
• Patient population
• Inclusion / exclusion criteria
• Conduct of the study
• Data handling
• Statistics
• (CTA)

Ethics approval / licence

Regardless of the country of origin, all clinical investigators describing human research must abide by the Ethical Principles for Medical Research Involving Human Subjects outlined in the Declaration of Helsinki, and adopted in October 2000 by the World Medical Association. This document can be found at http://www.wma.net/en/30publications/10policies/b3/. Investigators are encouraged to read and follow the Declaration of Helsinki. Clinical studies that do not meet the Declaration of Helsinki criteria will be denied peer review. If published research is subsequently found to be non-compliant it will be withdrawn or retracted.

On the basis of the Declaration of Helsinki, the *British Journal of Anaesthesia* requires that all manuscripts reporting clinical research state in the first paragraph of the Methods section that:

• The study was approved by the appropriate Ethics authority.
• Written informed consent was obtained from all subjects, a legal surrogate, or the parents or legal guardians for minor subjects, or that the requirement for written informed consent was waived by the ethics committee.

Human subjects should not be identifiable. Do not disclose patients' names, initials, hospital numbers, dates of birth, or other protected healthcare information. Keep copies of ethics approval and written informed consents. In unusual circumstances the editors may request blinded copies of these documents to address questions about ethics approval and study conduct.

The title of this section should be 'Methods'. 'Materials and methods' or 'Patients and methods' should not be used. While brevity is essential, the methods must be described in sufficient detail to allow the experiment to be interpreted, and repeated if necessary, by the reader. Previously documented standard methods need not be recounted in detail, but appropriate reference to the original should be cited. Where the programme of research is complex such as might occur in a cardiovascular study in animals, it may be preferable to provide a table or figure to illustrate the plan of the experiment, thus avoiding a lengthy explanation.

Sometimes detailed laboratory techniques may be filed separately in a recognized library and a note to this effect given in the manuscript. Where measurements are made, an indication of the error of the method in the hands of the author should be given. The name of the manufacturer of instruments used for measurement should be given with an appropriate catalogue number or instrument identification (e.g. Radiometer PHM 7). The manufacturer's town and country must be provided. In the case of solutions for laboratory use, the methods of preparation and precise concentration should be stated.

Patients

Data on the mean age (range), weight, sex, height, criteria for selection, etc. (*patient characteristics, not demographics*) should be presented, with an indication of the general state of health and type of operation being undertaken. Animal data on sex, strain and weight should be included. Although it is usually possible to make such a statement in a short paragraph, more complex information may be preferable as a table. However, tables and figures are expensive to produce and should not be used unnecessarily. Where it has been necessary to seek permission from the patients for the type of study being undertaken, this should be indicated.

Statistical analysis

Statistical methods must be described with enough detail to enable a knowledgeable reader with access to the original data to verify the report and results. Where possible, findings should be quantified and presented with appropriate indicators of measurement error or uncertainty (such as confidence intervals). Confidence intervals provide a more informative way to deal with a significance test than a simple *P* value. A power analysis should be performed before starting the study to determine the number of subjects which need to be studied in each group to detect a given change. Please note that a power analysis based on the primary end-point will not necessarily be applicable to any secondary measures.

It is recommended that authors seek appropriate statistical advice before starting their study, to ensure that the structure and planned recruitment is adequate to answer the question set.

Results

Guidance for this section includes;
• Must be factual
• Relate to aims
• Logical order
• State significances
• Negative findings

Description of experimental results should be concise. They should be presented in a factual manner and related to the aim of the study. It is often useful to present the results in the order described in the Methods section. Data should not be repeated unnecessarily in text, tables and figures (see below), and unwarranted numbers of digits should be avoided (Example: *the mean dose of propofol was 2.1 mg kg* $^{-1}$ *rather than 2.0897 mg kg* $^{-1}$). It may not be necessary to provide all the data from a complex study: only those values which are essential to the communication should be given. However, results should be presented in a manner so that the reader can check the statistical inferences. If the data are so numerous that this is not possible, the editor must be sent a full set with the submission of the original manuscript and the readers should be informed as to where they can obtain a similar full set of results. Where appropriate, for example in a pharmacokinetic study, more extensive sets of data can be included as an appendix with the on-line version of the article. If authors wish to make use of this facility, they should state this in the submission letter and upload the data as a separate file. The editor has the right to request the original data collected. In the results section there should be no attempt at a discussion of the findings.

Tables and figures

Figures and Tables are often useful to present either complex or extensive data in a more easily understandable form. However, authors are cautioned against unnecessary use of tables and figures. A useful approach is to prepare the raw data in the form of tables and then decide which data are to be presented in the article. The author should then decide whether the essential data be presented succinctly in the text. If not, the essential tables/ figures should be prepared. To illustrate this with examples: *a study outcome which compares two measurements in two groups can easily be presented as text, a comparison of arterial pressure and heart rate changes at five timepoints in two groups would be appropriate as a table and the same measurements in comparing three groups may be better as a figure.*

Tables and figures are important communications and should be accompanied by a legend which makes it self-explanatory. However, the legend must not contain experimental details, which should be given in the methods section.

The use of a figure should be considered only where a figure will present the data more clearly than is possible in a table or when an important trend or comparison has to be made for which a graphic presentation is clearly superior to a table or text.

The authors should decide which form they wish to present data in. Please note the limitation given above on the number of figures/tables permissible for each article type. Duplication of data by including it as a table and as a figure is unnecessary and wasteful.

Authors are advised to note the limitation on the number of figures/tables given above (4-6 tables or figures, in total) for clinical and laboratory. The use of multiple small figures submitted as one figure (for example Figure 1 a-f) is discouraged as when reduced to printed size these may not be clear. Authors are strongly advised to be selective in their use of figures and tables.

For further guidance on the format of tables and figures, see below. It is recommended that the author refers to previous issues of the journal regarding appropriate style.

Discussion

This is an important part of the manuscript but it should not be too long, perhaps one third of the total length of the paper. This requires discipline by the author for two reasons: first, they may feel that the task is nearly completed and that they are subject to fewer constraints; second, many authors seem to wish to read into their data more than is actually there.
It is suggested that the discussion should normally follow the pattern below:

• State main findings
• How do they fit in with previous studies
• Why are they different / same
• What it adds to knowledge of subject
• Weaknesses in study
• Future studies
• Conclusions

State main findings
This does not mean a repetition of all the results with their statistics. It should provide a concise overview of the study. For example, ' *Drug X produced a greater haemodynamic change on induction of anaesthesia than occurred with drug Y, resulting in a greater fall in arterial pressure and a higher incidence of tachycardia* '.

How do they fit in with previous studies

This section should relate directly to the statements made in the Introduction and qualify you finding in relation to the previous studies of the subject. For example, mention any important uncertainties in the methods of measurement. In laboratory studies, try to relate the concentrations used to those encountered clinically.

Why are they different / same

Deductions which may explain important differences between the data of the present study, and the data of previous studies. The author should avoid excessive speculation in this section. It is quite reasonable to suggest possible explanations for your findings and any differences from previous studies but the 'missing parts' of such reasoning must be acknowledged.

What it adds to knowledge of subject

This can summarise the previous sections by pulling together the implications of your main findings, studies by other workers and their combined contribution to our knowledge of the subject. This should not be just another repetition of the results and preceding discussion but more of an expanded conclusion.

Weaknesses in study

It is appropriate to briefly acknowledge any limitations of your study at this point. Examples here could include the patient population, limitations of analytical tests, patients lost to follow-up. Authors are advised to be honest but succinct in this section.

Future studies

A logical follow on to the two previous sections is to identify future studies that would address some of the potential explanations and limitations discussed earlier. This should again be concise. An extensive list of future studies undermines you own study: i.e. has it answered anything if there are still so many questions?

Conclusions

Conclusions from the present study. The original contribution to knowledge from the present study is stated. A common fault here is to overstate the findings from a study. For example, *if you have studied the effect of a new drug in an animal model you cannot draw any conclusions at all about its effect in humans and likewise if you studied ASA 1 and 2 patients you cannot comment on its use in critically ill patients.*

It *may* be appropriate to give the implications of the conclusions for anaesthetic practice and the indications for further enquiry in this area of interest.

Authors should remember at all times, but especially in writing the discussion, that they will spoil their manuscript by excessive length. A discussion of more than three pages is often too long.

Declaration of interests

It is essential to acknowledge all sources of financial assistance, and any potential material benefit expected from publication of the work. Also, please describe the role of the study sponsor, if any, in study design; collection, analysis and interpretation of data; writing the report; and the decision to submit the report for publication.

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Agencies should be separated by a semi-colon (plus 'and' before the last funding agency)

Where individuals need to be specified for certain sources of funding the following text should be added after the relevant agency or grant number 'to [author initials]'.

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References

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Chapter in a book. The reference for an article forming part of a book should take the form:
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● ○ ■ ⁜ ▼ ▲ ♦ ◊ V X +

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Particular problems have arisen in relation to the notation of units which was introduced at the same time as the change to the SI system. Avoid the use of the solidus (/) in favour of various units of the expression set on one line. In the case of expressions 'below the line' superscript -1, -2, etc. as appropriate is given. Thus for drug dosage use mg kg^{-1} not mg/kg.

Spelling and grammar

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Section 3: Draft article

Ultrasound-assisted versus landmark-based spinal block performance in emergency caesarean delivery in obese patients at a central hospital

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Running title: Ultrasound-assisted spinals in obese parturients

Keywords: Africa; emergency surgical procedures; obesity; obstetric anaesthesia; spinal anaesthesia; ultrasonography, interventional

Abstract

Background

An ultrasound-assisted spinal block technique for obstetric anaesthesia has not been studied in an African population or during emergency caesarean delivery (CD). The aim of the study was to assess the effect of preprocedural neuraxial ultrasound on the performance of spinal blockade in obese parturients undergoing spinal block for emergency CD in a central hospital in Johannesburg, South Africa.

Methods

A two-armed, prospective comparative contextual study design was used. Adult women booked for emergency CD under spinal block had preprocedural ultrasound performed before being randomised to either a landmark-based group (LMG) or an ultrasound-assisted group (USG). The USG had identified landmarks marked to assist the anaesthetist. The primary end-points were first-pass success rate, difficult spinal block rate, procedure time, number of needle punctures and needle passes. Secondary end-points include the intervertebral spaces attempted, the predicted ultrasound distance and actual needle depth.

Results

Thirty-six participants were recruited between January and February 2020. The USG was associated with a shorter procedure time (48s versus 97s, $p<0.05$) and fewer needle passes (3 versus 5.5, $p<0.05$). The LMG had a greater percentage of blocks performed at higher intervertebral spaces (L1/2 or L2/3) compared to the USG (66.7% versus 11.1%, $p<0.05$). The predicted ultrasound distance correlated well with the actual needle depth ($r = 0.86$, 95% CI 0.65 – 0.95) with a mean difference of 10 mm (range 0 – 25 mm).

Conclusion

Preprocedural ultrasound was associated with a statistically significant improvement in some technical measures of spinal block performance when used for emergency CD in an African population.

Introduction

The World Health Organization (WHO) has declared safe obstetric anaesthesia as a global healthcare priority (1), a priority shared by the South African government (2). A spinal block is the recommended neuraxial anaesthetic (NA) technique for caesarean delivery in South Africa (3). NA is considered safe for use in obstetric anaesthesia, with a low incidence of permanent major harm (4). Adverse effects include failure of NA (5), which is often followed by a need to convert to general anaesthesia, putting patients at a high risk for associated complications (6). The risk of failure of NA is higher if the spinal block is more difficult to perform (7). Difficulty in performing a spinal block is inconsistently defined in the literature, but generally involves a greater than normal number of needle punctures or passes (8-10), a greater number of intervertebral spaces attempted (8) or a longer procedure time (10). Independent factors associated with difficult NA include poorly palpable spinal landmarks and poor ability to flex the back. These are subjective clinical measures, but are predicted by the presence of obesity or spinal abnormalities in the parturient (10).

In 2016, the WHO estimated the prevalence of adult female obesity in South Africa at 39.6%, this compared to the worldwide prevalence of 15.1% (11). Obesity in pregnancy is associated with increased risk from general anaesthesia (6, 12), with a preference for a NA technique if no contraindications exist (13). In contrast, the prevalence of spinal abnormalities during pregnancy is very low, reported as less than 0.05% (14).

Point-of-care ultrasound has gained increasing utility in the perioperative setting, with ultrasound-assisted NA gaining a sound evidence base in obstetric anaesthesia (15). Preprocedural ultrasound-assisted NA involves the use of an ultrasound to identify points for needle entry, as well as determining target depth and needle entry angle (16). A preprocedural ultrasound-assisted technique has been shown to improve first-pass success, reduce the number of skin punctures and passes and reduce the risk of spinal block failure (17). It shows improved accuracy in correctly identifying intervertebral spaces, potentially reducing the risk of neurological damage (18). It also shows a trend towards fewer minor adverse

events, such as backache (19). These findings have been demonstrated in those with risk factors associated with difficult NA, such as obesity (20, 21).

No studies assessing the utility of preprocedural ultrasound in patients undergoing a spinal block for emergency caesarean delivery or in a predominantly African population could be identified. Given the high rate of maternal obesity in the South African population (22), difficulty in performing NA is anticipated. However, it remains unknown how an ultrasound-assisted spinal block performs in an obese African population undergoing emergency caesarean delivery. The aim of this study was to assess the effect of the ultrasound-assisted technique on the technical measures of spinal block performance for emergency caesarean deliveries in obese patients at Chris Hani Baragwanath Academic Hospital (CHBAH), as compared to the standard landmark-based technique.

Methods

This was a two armed, prospective comparative contextual study design was used. The study was performed at CHBAH, a 2 888-bed central hospital which operates two 24-hour obstetric emergency theatres. Annually, 65 000 surgeries are performed at CHBAH, approximately 8 000 – 10 000 of which are caesarean deliveries and the majority of which are booked as emergencies.

The study was approved by the University of the Witwatersrand Human Research Ethics Committee (Medical) (M190614). The study was registered with the Pan African Clinical Trials Registry (PACTR202001800912516, registered 20 October 2019). Written informed consent was obtained from patients and anaesthetists taking part in the study.

Study population

The study population consisted of ASA physical status 1 – 3 patients, aged ≥ 18 years presenting for emergency caesarean delivery with a spinal block planned as the primary anaesthetic. To be included in this study patients' BMI at first antenatal weighing had to be ≥ 30 $kg.m^{-2}$. In addition, the non-specialist anaesthetist performing the spinal block was required to have at least two years of supervised anaesthesia experience. Exclusion criteria included the presence of spinal block contraindications, patient's inability to communicate in English, inability to adequately perform the ultrasound imaging protocol, excessive number of needle passes and spinal block failure. No single anaesthetist could not take part in the study more than twice, in order to reduce bias resulting from individual skill. In consultation with a biostatistician using Stata 14.2 (StataCorp, USA) software, a sample size of 18 successful spinal blocks per group was determined. The calculation was based on a first-pass success rate in the ultrasound-assisted group (USG) of 92% and in the landmark-based group (LMG) of 44% from a similar study (23), giving a power of 90% and an alpha of 0.05.

Study protocol

All patients entering the theatre complex were screened for eligibility. Based on departmental data, patients are routinely brought early to the theatre admission area in this hospital, on average 35 – 50 minutes before surgery. Patients were enrolled during this period in order to ensure the study would not result in any delay in care. Upon enrolment, a clinical assessment and ultrasound imaging were performed by one author(BK). The markings on the patient's back were made using a fluorescent marker that could only be seen using an ultraviolet light. The patient was then randomised to either the LMG or the USG using a randomisation protocol. A set of computer-generated numbers (generated by www.random.org) were placed in opaque envelopes and picked by a theatre staff member not affiliated with the study. Once a theatre became available, the patient was taken in and a spinal block performed by the anaesthetist. If a theatre became available prior to completion of the clinical or ultrasound assessments, the patient was excluded from the study in order to prevent delays in patient care. In the LMG, anaesthetists would use landmarks identified through clinical inspection and palpation to guide needle insertion, as shown in panel A in Figure 3.1. In the USG, the landmarks delineated through ultrasound were made visible prior to theatre entry using an alcohol-resistant Accura permanent marker (Claro, India). These markings would then be used by the anaesthetist to identify needle entry points, as shown in panel C in Figure 3.1. The spinal block was performed with a 25G spinal needle with the patient sitting in a standard position with legs elevated on a chair, back flexed, back and shoulders relaxed and elbows placed on knees (24). A safety limit of 21 needle passes was used, after which the fluorescent marking would be made visible to the anaesthetist if they were in the LMG (panel B in Figure 3.1), and the patient excluded from the study. This was to ensure no parturient was exposed to an excessive number of needle passes required for a spinal block. This safety limit was based on the 66th centile of needle passes in a similar patient cohort (9). Finally, any spinal block that required conversion to a general anaesthetic prior to surgical delivery of the foetus would be considered failed and the patient would be excluded from analysis.

Clinical assessment protocol

The patient would be clinically assessed by the author (BK) performing the ultrasound. The degree of back flexion and palpation of the spine were graded according to Ellinas and co-workers (10). Back flexion was graded as 1) convex, 2) straight and 3) concave. Palpation was graded as 1) easily palpable/visible, 2) Palpable but not visible, 3) poorly palpable and 4) impalpable. The presence of either grade 2 or 3 flexion or grade 3 or 4 palpation identified the patient as having a predicted difficult spinal.

Ultrasound imaging protocol

All patients were positioned in the same standard position as for the spinal block while performing ultrasound imaging. The author (BK) performing the ultrasound had accreditation in point-of-care ultrasound and experience with > 50 ultrasound-assisted NAs. A GE Logiq e ultrasound machine (GE, USA) with a C1-5 curvilinear probe was used to identify spinal anatomy. All markings were made using an 8280 Special Securitas UV marker (Edding, Germany), made visible during marking using a fluorescent ZA-490 UV flashlight, 9 LED (Zartek, South Africa). An oblique parasagittal view of the spine was obtained, with progressive identification and marking of the sacrum and the midpoints of the L5/S1, L4/5, L3/4 and L2/3 spaces using horizontal lines 5 – 10 cm away from the midline. The ultrasound depth (UD) and angle of entry were also noted on each patient for each space. Upon reaching the L2/3 space, the probe was turned to a transverse orientation and the midline of L3/4 was identified and marked 5 – 10 cm above the L2/3 space. If these structures could not be identified on ultrasound, the patient was excluded from the study.

Data collection

Following patient enrolment, patient characteristics, grade of flexion, grade of palpation and ultrasound parameters such as UD at each space, anticipated needle angle and time to perform ultrasound imaging were all recorded. During the spinal block procedure, number of needle punctures, number of needle passes,

initial intervertebral space (IVS), number of IVSs attempted, final IVS used, procedure time and the needle's actual depth (AD) were recorded. Both the UD and AD were noted to the nearest 5 mm. Needle punctures were defined as the number of times the needle was inserted through the skin. Needle passes were defined as the number of times the needle was advanced then withdrawn through the tissues. Initial IVS was the IVS entered with the first needle puncture, and final IVS was the IVS resulting in cerebrospinal fluid flow through the spinal needle. Procedure time was from the time of first needle puncture to sufficient cerebrospinal fluid flow to perform the spinal block. AD was calculated by subtracting skin-to-hub needle length from total needle length.

The primary end-point was first-pass success rate. The primary outcomes were technical measures of spinal block performance, namely first-pass success rate, difficult spinal block rate (> 10 passes), number of needle punctures, number of needle passes and procedure time. Secondary outcomes were initial IVS, number of IVS's attempted, final IVS and the needle's AD.

Statistical analysis

Data were analysed in consultation with a biostatistician using the statistical program STATA version 14.2 (StataCorp, USA). Categorical variables were described using numbers and percentages. Continuous variables were described using means and standard deviations if normally distributed, or medians and ranges or interquartile ranges. Comparisons of measures of spinal block performance between groups were made using the independent t-test or the Mann-Whitney U-test. The comparison of patient factors (anticipated difficult spinal block) with measures of spinal block performance was made using Fisher's exact test. Correlation between UD and AD was calculated using Pearson's Correlation Coefficient. A p-value of ≤ 0.05 was considered statistically significant.

Results

During January to February 2020, 223 patients were assessed for eligibility. Of these, 43 patients were enrolled, with 7 excluded prior to analysis. The 3 protocol violations were due to delays from inadequate equipment availability of extra-length spinal needles and procedural interruptions by staff uninvolved in the case. Thirty-six patients were randomised, 18 per group. The sample realisation is summarised in Figure 3.2. The time to perform the ultrasound examination, from probe-to-patient contact until end of sonographic examination, ranged from 2 to 4 minutes.

Patient characteristics are presented in Table 3.1. There was no significant difference between groups with respect to age, gravidity, parity, gestational age, and anthropometric measurements.

The primary and secondary outcomes pertaining to technical measures of spinal performance for each group are shown in Table 3.2. There was a statistically significant difference in the number of needle passes and the procedure time between the groups. Regarding intervertebral spaces used during spinal block, the LMG had 3 successful attempts at L1/2 or higher, while there were none higher than L2/3 in the USG. Comparing the rates of low risk and high risk initial and final intervertebral spaces demonstrated a significant difference between the two groups.

The comparison between predicted easy and predicted difficult patient groups is summarised in Table 3.3. There was a statistically significant difference in the BMI between the two groups, but there were no significant differences in the measures of spinal block performance between the groups.

The correlation ($r = 0.86$: 95% CI 0.65 – 0.95) between UD versus the AD for each patient is shown in Figure 3.3. The UD median was 65 mm (range 45 – 100 mm), compared to the AD median of 75 mm (range 50 – 110 mm). The median difference between the UD and AD was 10 mm (range 0 – 25 mm) and in all instances the UD was less than or equal to the AD.

Of note, all 3 patients in whom the needle pass safety limit was exceeded were in the LMG. These 3 patients were excluded from final analysis, but the further needle punctures and passes were noted once ultrasound markings were made visible. In all 3 instances, the spinal space was reached within 7 further needle passes without a need to convert to general anaesthesia.

Discussion

The principal finding in this study is that preprocedural ultrasound-assisted spinal block resulted in a reduction in both the procedure time and the number of needle passes. This is consistent with previous studies of both the obstetric population generally (25) and the obese obstetric population specifically (9). However, an average procedure time and needle pass difference of 49 seconds and two needle passes is of questionable clinical value, particularly when an ultrasound-assisted technique may take a few minutes to perform.

Instead, these reductions in procedure time and needle passes should be viewed in the context of the study protocol. None of the USG patients required more than 10 needle passes. This would classify all USG patients as being easy spinal blocks, compared to four of the LMG patients classified as difficult. Additionally, if the three patients who were excluded in the LMG due to a breach of the safety limit for needle passes are considered, and the fact that a successful spinal block was performed within seven further passes once the ultrasound markings were revealed, the utility of preprocedural ultrasound increases. Perlas and colleagues (19) reported a number needed to treat of 16 to prevent a NA failure. Given the high risk during general anaesthesia in the obese pregnant population, a sacrifice of a few minutes to improve the NA success rate may be clinically critical, particularly in the emergency setting.

This is especially important to consider in a resource-constrained setting, where anaesthesia-related deaths are associated with failed NA (26). Acquisition and maintenance costs are significant barriers to equipment availability in developing nations (27). A single point-of-care ultrasound device, with capabilities to assist with vascular access, cardio-respiratory assessment and NA (15) would hold distinct advantage over requiring multiple separate different devices to perform the same functions.

The results also confirmed the improved accuracy of ultrasound-assisted NA. In the LMG, IVSs entered were significantly more likely to be either L1/2 or L2/3, potentially putting this group at a higher risk for neurological injury as the level of the conus medullaris may range from T12 to L3 (28). Ultrasound has shown level

IIa evidence in improving identification of lumbar spaces, even in obese individuals (19). The use of ultrasound may potentially be associated with improved patient safety, as it assists with the identification of a safer spinal needle entry point, away from the conus medullaris. Given the low reported incidence of neurological injury (4), a far greater sample size would be required to show improved safety.

Clinical assessment of the spine did not appear to be superior in predicting difficult spinal blockade in this study. The significant difference in BMI between the 'predicted easy' and 'predicted difficult' spinal block groups reiterates the relationship between obesity and predictors of difficult spinal block found in a previous study (10). De Oliveiro Filho and colleagues (7) developed a correlation model to stratify patients at risk of difficult neuraxial blockade, but the model achieved only a modest predictive value, and the authors themselves suggest that "other factors may contribute to success". Obesity and the presence of spinal abnormalities remain the most useful predictors of difficulty in NA (10). Until more data becomes available, it remains prudent to use the BMI as a tool to identify who may benefit from an ultrasound-assisted technique, as suggested by Li and co-workers (9).

The results showed that the predicted ultrasound depth correlated well with actual needle depth, comparable to a previous study with a similar Pearson's correlation coefficient ($r = 0.709$) (23). Ultrasound consistently underestimated spinal target depth, a finding in keeping with conclusions from the meta-analysis by Perlas and colleagues (19), likely due to the compressive effects of the ultrasound probe.

Limitations of this study included the lack of blinding, but the visual nature of the intervention precluded it. Investigator blinding was partially achieved by only randomising patients after clinical and ultrasound assessments were performed, limiting potential selection bias during those assessments.

The exclusion of anaesthetists who had been included in the study two times prior increased the generalisability of the study findings, as no single anaesthetist's ability (or inability) at performing a spinal block could bias the results. A future study could assess whether similar benefit in procedure time and needle passes was observed if the trainees themselves performed the ultrasound in the

emergency setting. It would also be interesting to assess whether a similar preprocedural ultrasound protocol would be of benefit if the anaesthetist performing the block was a specialist who had already completed training.

This study demonstrated the utility of preprocedural ultrasound for neuraxial anaesthesia in a population of African ethnicity and in the emergency setting for the first time, increasing the generalisability of previous findings. It is encouraging that the study findings were consistent with other studies in non-African populations and during elective surgery (9, 20, 29).

Conclusion

This study provided further evidence for the use of ultrasound in a population associated with difficult spinal anaesthesia, as it improved procedure time and the number of attempts. Preprocedural ultrasound also resulted in a lower incidence of entry into high IVSs such as the L1/2 and L2/3 spaces and may thus be associated with improved accuracy. The study generates a signal that preprocedural neuraxial ultrasound in emergency caesarean deliveries is of benefit, particularly in a population at higher risk of complications from conversion to general anaesthesia. The decision to accept the time cost of performing an ultrasound examination of the spine should be contextualised to the correct patient and health setting.

Authors contributions

B.K. : conceptualised the study design, wrote the study protocol, recruited patients, collected data, analysed the data and wrote the first draft of the article.

J.S. : assisted with study design, article drafting, and providing research and writing support.

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

D.N. : assisted with study design, data interpretation and article drafting.

Declaration of interests

The authors declare that they have no financial or personal relationships which may have inappropriately influenced them during the drafting of this paper.

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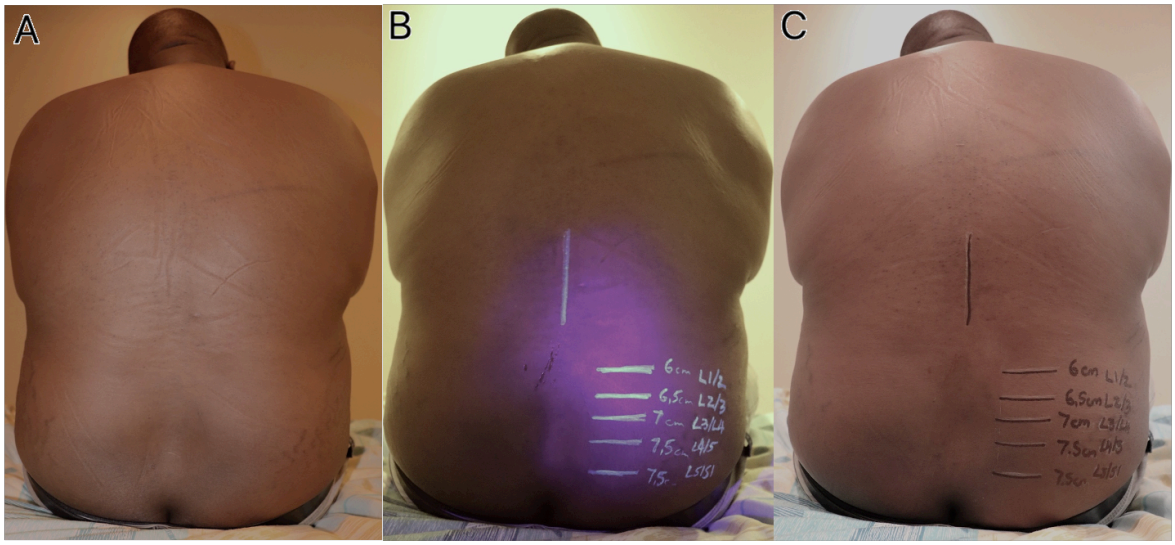


Fig 3.1 Pictures showing simulated appearances of patients' backs under different study conditions

(A) depicts a patient's back with 'invisible' ultraviolet markings after ultrasound assessment, as would be seen if the patient was randomised to the landmark-based group. (B) depicts a patient's back as it would appear if a patient randomised to the landmark-based group had had the needle pass safety limit exceeded and the 'invisible' markings were then made visible using the ultraviolet flashlight. (C) depicts a patient's back with the markings from the ultrasound examination made visible with a black marker, as would be seen if the patient was randomised to the ultrasound-assisted group.

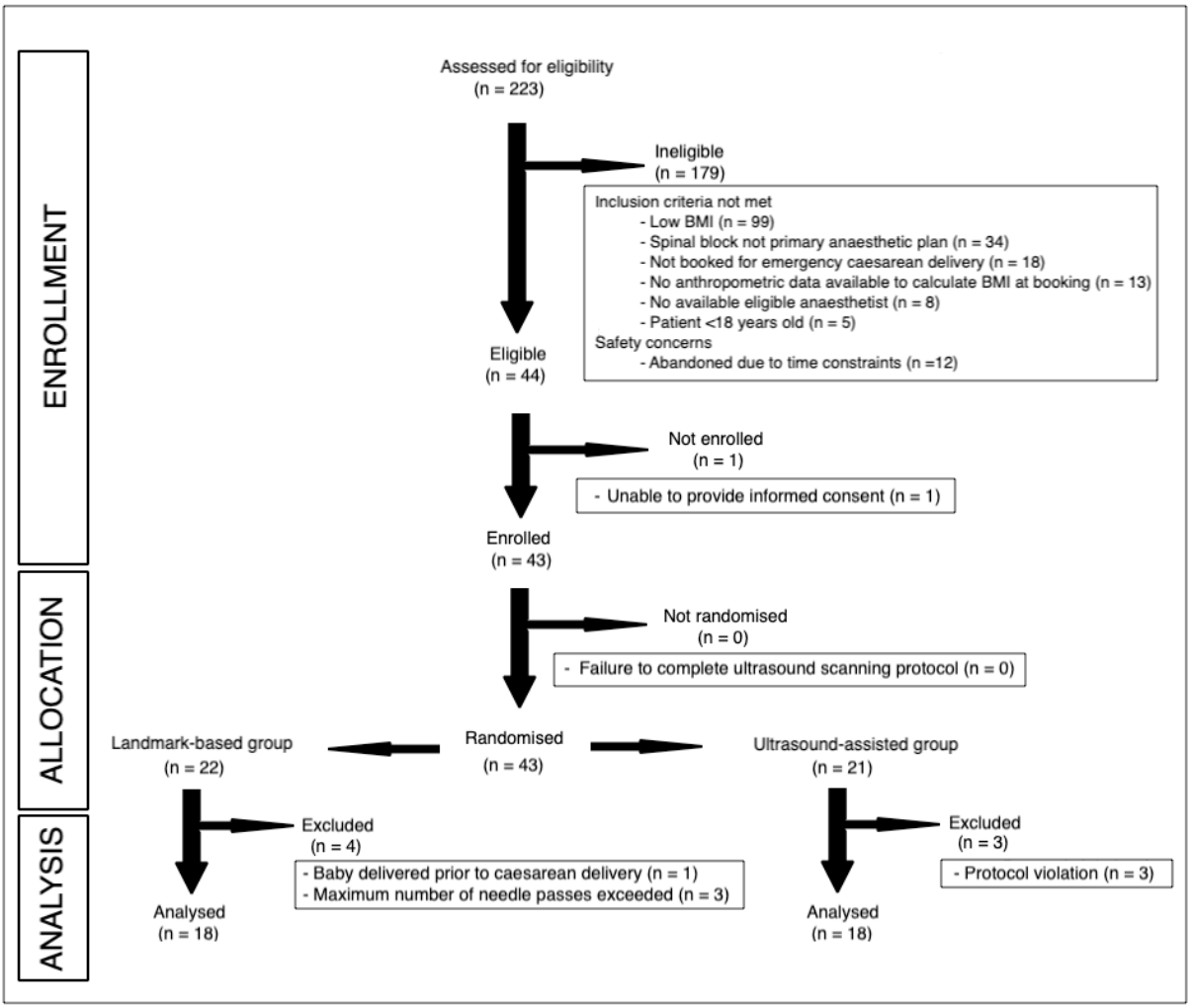


Fig 3.2 Sample realisation

BMI = Body mass index ($kg.m^{-2}$)

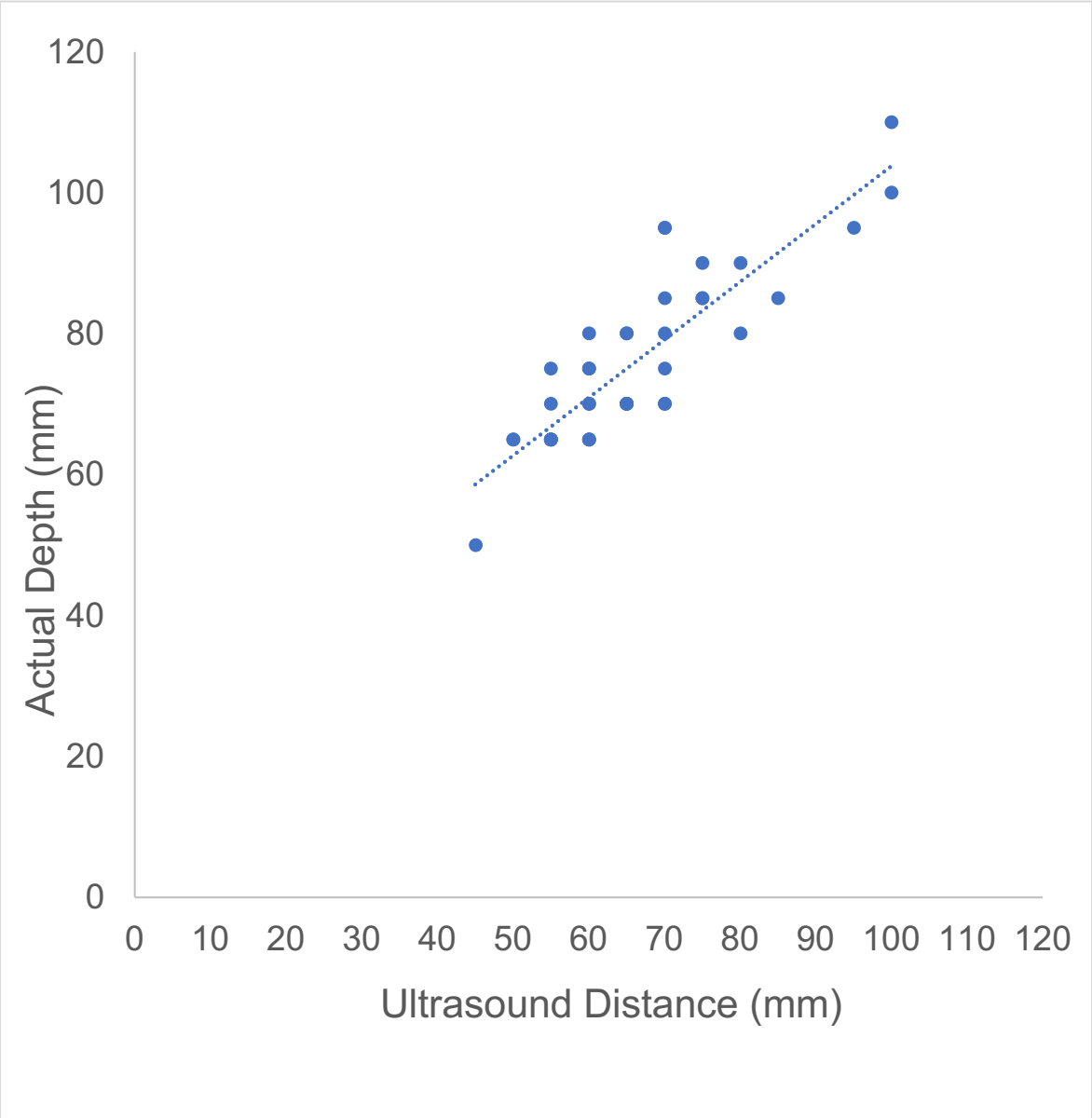


Fig 3.3 Ultrasound distance versus actual depth

Table 3.1 – Patient characteristics

LMG = landmark-based group; USG = ultrasound-assisted group; SD = standard deviation; IQR = interquartile range; BMI = body mass index

	LMG (*n* = 18)	**USG** (*n* = 18)	*p*-value
Age [years; mean (range)]	31.4 (22 – 45)	32.1 (23 – 42)	0.372
Gravidity [n; median (range)]	2.5 (1 – 6)	3 (1 – 8)	0.097
Parity [n; median (range)]	1 (0 – 4)	2 (0 – 4)	0.192
Gestational age [weeks; mean (SD)]	38.7 (1.9)	37.2 (4.4)	0.205
Height [m; mean (SD)]	159.9 (6.6)	159.6 (5.18)	0.918
Weight [m; median (IQR)]	90.8 (85.5 – 99.5)	84 (78.4 – 104)	0.192
BMI [$kg.m^{-2}$; median (IQR)]	36.0 (33.1 – 38.9)	32.7 (30.8 – 41.4)	0.127
Obesity grade [n (%)]			
1 – BMI 30.0 – 34.9	7 (38.9)	11 (61.1)	
2 – BMI 35.0 – 39.9	8 (44.4)	2 (11.1)	
3 – BMI $\geq$ 40.0	3 (16.7)	5 (27.8)	0.083

	n (%)
Indication for emergency caesarean delivery	
Suspected foetal distress	24 (66.7)
Previous caesarean delivery	14 (38.9)
Abnormal progress	5 (13.9)
Abnormal lie	3 (8.3)
Pre-eclampsia or gestational hypertension	3 (8.3)
Twin pregnancy	2 (5.6)
Number of indications for emergency caesarean delivery	
Single indication	23 (63.9)
Two indications	11 (30.6)
Three indications	2 (5.5)

Table 3.2 – Technical measures of spinal block performance

LMG = landmark-based group; USG = ultrasound-assisted group;

IVS = intervertebral space; IQR = interquartile range

	LMG (*n* = 18)	**USG** (*n* = 18)	*p*-value
First-pass success rate [n (%)]	2 (11.1)	4 (22.2)	0.658
Difficult spinal block rate [n (%)]	4 (22.2)	0 (0)	0.104
Number of needle punctures [median (range)]	1 (1 – 3)	1 (1 – 3)	0.334
Number of needle passes [median (range)]	5.5 (1 – 20)	3 (1 – 8)	0.026*
Procedure time [s; median (IQR)]	97 (42 – 105)	48 (28.5 – 78.8)	0.049*
No of IVSs attempted [n (%)]			
1	17 (94.4)	17 (94.4)	
2	1 (5.6)	1 (5.6)	1.000
Initial IVS attempted [n (%)]			
High risk	11 (61.1)	2 (11.1)	
L1/L2 or higher	3 (16.7)	0 (0)	
L2/3	8 (44.4)	2 (11.1)	
Low risk	7 (38.9)	16 (88.9)	0.005*
L3/4	7 (38.9)	15 (83.3)	
L4/5	0 (0)	1 (5.56)	
Final IVS used [n (%)]			
High risk	12 (66.7)	2 (11.1)	
L1/L2 or higher	3 (16.7)	0 (0)	
L2/3	9 (50)	2 (11.1)	
Low risk	6 (33.3)	16 (88.9)	0.002*
L3/4	6 (33.3)	15 (83.3)	
L4/5	0 (0)	1 (5.6)	

*denotes statistically significant difference

Table 3.3 – Comparison between predicted easy and predicted difficult spinal block performance

BMI = body mass index; IQR = interquartile range

	Predicted easy (*n* = 12)	**Predicted difficult** (*n* = 24)	*p*-value
Landmark-based group [n (%)]	5 (41.7%)	13 (54,2%)	
Ultrasound-assisted group [n (%)]	7 (58.3%)	11 (45.8%)	0.725
BMI [$kg.m^{-2}$; median (IQR)]	31.0 (30.3 – 35.7)	36.4 (32.8 – 42.6)	0.007*
First-pass success rate [n (%)]	3 (25%)	3 (12.5%)	0.347
Difficult spinal block rate [n (%)]	10 (83.3%)	22 (91.7%)	0.588
Number of needle punctures [median (range)]	1 (1 – 3)	1 (1 – 3)	0.356
Number of needle passes [median (range)]	3 (1 – 11)	5 (1 – 20)	0.245
Procedure time [s; median (IQR)]	48 (21.5 – 83.5)	85 (35.75 – 128)	0.082

*denotes statistically significant difference

Section 4: Proposal

Ultrasound-assisted versus landmark-based spinal block performance in emergency caesarean delivery in obese patients at a central hospital

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4.1 Introduction and problem statement

The World Health Organization (WHO) has declared safe obstetric anaesthesia as a global healthcare priority (1), a priority shared by the South African government (2). Anaesthesia-related maternal mortality has decreased over the past several decades, in part due to a shift away from general anaesthesia (GA) towards neuraxial anaesthesia (NA) as the anaesthetic modality of choice for caesarean delivery (3-5).

A notable 20% of anaesthetic-related maternal mortality in South Africa remains the result of complications from GA (6). The highest risk associated with a GA is during maternal airway management, with common adverse respiratory events including aspiration, hypoxaemia, and failed intubation (7). Failure of NA is often followed by the need to convert to a GA, putting patients at high risk for the above complications.

A spinal block is the recommended NA technique for caesarean delivery in South Africa (8), with a standard “landmark-based” technique that involves the palpation of landmarks to determine a safe needle entry point and trajectory (9). NA is considered safe for use in obstetric anaesthesia, with an incidence of permanent major harm of between 1 in 80 000 – 320 425 NAs (10). Reported minor and major adverse effects include failure of regional anaesthesia (11), backache, post-dural puncture headache, neurologic injury, infective spinal canal complications, high spinal, cardiovascular collapse, cardiac arrest, and death (12).

The risk of adverse events is higher if the spinal block is more difficult (13). Difficulty is defined by a greater than normal number of needle punctures, needle passes or intervertebral spaces used, or where the time to complete the procedure is increased (14, 15). Independent factors associated with difficult NA include poorly palpable or impalpable spinal landmarks and poor ability to flex the back into a concave shape. These are subjective clinical measures, but are predicted for by the presence of obesity or spinal abnormalities in the parturient (13, 16).

In 2016, the WHO estimated the prevalence of female obesity in South Africa to be 39.6%, compared to the worldwide prevalence of 15.1% (17). In one small

Johannesburg based study (18), prevalence was higher (44%) in the obstetric sub-population. There is a paucity of recent data regarding the epidemiology of spinal abnormalities in obstetric patients, but the available literature suggests a prevalence of between 0.02 – 0.7% (19). Both obesity and spinal abnormalities are associated with an increased risk of adverse events from GA, and therefore a NA technique is preferable if no other contraindications exist (20, 21).

Point-of-care ultrasound has gained increasing value in the perioperative setting over the past two decades (22). It has both diagnostic and periprocedural uses and has been shown to decrease morbidity related to a variety of procedures (23). Obstetric perioperative point-of-care ultrasound uses include vascular access guidance, perioperative echocardiography, gastric volume assessment, airway management and, notably, NA facilitation (24).

Preprocedural ultrasound-assisted NA involves the use of an ultrasound to identify points for needle entry without the use of palpation. Additional information includes target depth and skin-target angle of entry (25). It also shows improved accuracy in identifying intervertebral spaces that are low risk for neurological damage, as compared to the landmark-based technique (26).

A preprocedural ultrasound-assisted technique has been shown to increase first-pass success, reduce the number of skin punctures and passes, and reduce the risk of spinal block failure (27). It results in fewer minor adverse events, such as backache in the obstetric population (28). These findings have been proven in patients with risk factors associated with difficult NA (29, 30), but have also been demonstrated in patients without factors associated with difficulty (31-33). Although there has been research showing little or no benefit in measures of technical performance (34-37), many of these results have been influenced by methodological problems (27).

No studies assessing the utility of preprocedural ultrasound in patients undergoing emergency caesarean delivery or in a predominantly African patient population could be identified. Given the high rate of maternal obesity in our population (18), difficulty in performing NA is anticipated. It has been indicated that obesity can result in a decreased first-pass success rate; an increased number of skin

punctures; an increased number of needle passes; an increased incidence of minor morbidity; and an increased procedure time and failure rate. It is unknown how ultrasound-assisted spinal block performance compares to standard landmark-based performance in an obese population of African ethnicity undergoing emergency caesarean delivery.

4.2 Aim and objectives

4.2.1 Aim

The aim of this study is to assess the effect of the ultrasound-assisted technique on the technical measures of spinal block performance by anaesthetists in emergency caesarean deliveries in obese patients at Chris Hani Baragwanath Academic Hospital (CHBAH), as compared to the standard landmark-based technique.

4.2.2 Objectives

The primary objectives of this study are to describe and compare:

- the first-pass success rate
- the rate of difficult spinal block (> 10 needle passes)
- the number of needle punctures
- the number of needle passes
- the procedure time in the ultrasound-assisted and landmark-based groups.

The secondary objectives of this study are to:

- describe the initial intervertebral space used, number of intervertebral spaces attempted, final intervertebral space used during spinal block in each group
- describe the rate of initial and final passes attempted in high risk vs low risk spaces for both initial and final intervertebral spaces in each group
- compare patient factors (presence/absence of factors associated with predicted difficult spinal block) with technical measures of spinal block performance
- correlate the measured ultrasound distance to the actual needle depth.

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4.3 Research assumptions

The following definitions will be used in this study.

Anaesthetist: in this study is a qualified doctor working in the Department of Anaesthesiology as a medical officer or registrar with at least two years of supervised experience in anaesthesia. It has previously been shown that anaesthetists' ability to perform landmark-based spinal block approximated that of a specialist anaesthetist after two years of experience (38).

Ultrasound-assisted technique: a technique in which preprocedural ultrasound is used to mark spinal anatomical landmarks, needle entry points, depth to target and angle of entry, in order to facilitate a spinal block. In this study, the specific technique used is outlined in the data collection section of the proposal. In brief, it involves the initial use of a parasagittal oblique view to identify intervertebral spaces, their entry points and target depths, and the subsequent use of a transverse view to identify the midline and angle of entry. Following the ultrasound, the spinal block is performed using the identified points. This is done in the same patient position as during the ultrasound imaging protocol and the landmark-based technique.

Landmark-based technique: a procedure during which anatomical landmarks are visualised or palpated to demarcate the entry point and needle angle of entry for the spinal block. In this study, the patient is first positioned sitting with maximum back flexion to optimise palpation of landmarks. The intercristal line is identified by manually palpating the apices of the iliac crests bilaterally. The intersection of this line with the midline is used to identify the L3/4 intervertebral space and is the desired needle entry point (39). Following this, the spinal block is performed using the landmarks identified.

Technical measures of spinal block performance: these are aspects of how a spinal block is performed that allow for comparison between different techniques and users. In this study, they include first-pass success, difficult spinal block, the number of needle punctures, number of needle passes and procedure time.

First-pass success: the successful puncture of the subarachnoid space following a single needle puncture and needle pass.

First-pass success rate: the number of first-pass successes in a group over the total number present in that group.

Difficult spinal block: a spinal block requiring more than 10 needle passes to successfully reach the subarachnoid space (40).

Difficult spinal block rate: the number of difficult spinal blocks in a group over the total number present in that group.

Number of needle punctures: the number of times the spinal needle was withdrawn from the skin and reinserted.

Number of needle passes: the number of times the spinal needle is advanced, withdrawn and then redirected towards the subarachnoid space without exiting the skin.

Maximum allowable number of needle passes: in this study, this will be 21 needle passes. This number was derived from the study by Li et al. (40). It is based on data regarding the number of needle passes required to successfully reach the subarachnoid space using the conventional landmark-based technique in 40 obese parturients awaiting caesarean delivery. The mean (14.9) and standard deviation (16.8) were used to calculate the 66^{th} centile for the number of attempts (21.82).

Procedure time: the time from first insertion of the spinal needle through the skin to connecting the syringe for injection after free cerebrospinal fluid flow is noted.

Initial intervertebral space: the intervertebral space entered with the first needle puncture.

Final intervertebral space: the intervertebral space entered with the needle puncture resulting in successful cerebrospinal fluid flow.

Ultrasound distance: the distance from the skin to the posterior complex on the best sonographic view of that intervertebral space using a parasagittal oblique view of the spine.

Needle depth: the depth to which the spinal needle was inserted to successfully reach the subarachnoid space.

Obesity in pregnancy: defined by the WHO as a body mass index (BMI) of ≥ 30 $kg.m^{-2}$ at the first available antenatal visit weighing (41).

Ultrasound-assisted group: the patient group randomised to have the landmarks identified with the preprocedural ultrasound procedure marked with a visible marker. These will indicate to the anaesthetist the needle entry points, depth of target and angle of entry.

Landmark-based group: the patient group randomised not to have visible markings made after preprocedural ultrasound. The anaesthetist will therefore use the standard landmark-based technique to perform the anaesthetic.

Presence of factors associated with difficult spinal block: as per Ellinas et al. (16), the presence of either grade 2 or 3 back flexion or grade 3 or 4 palpation (Appendix A).

Absence of factors associated with difficult spinal block: as per Ellinas et al. (16), grade 1 back flexion and either grade 1 or 2 palpation (Appendix A).

4.4 Demarcation of study field

The study will be conducted in the obstetric theatre complex of CHBAH, affiliated to the Department of Anaesthesiology at the University of the Witwatersrand.

CHBAH is a 2888-bed central hospital. The hospital has 25 theatres, of which two are obstetric emergency theatres that operate 24 hours a day. On average 65 000 surgeries are done annually, of which approximately 8 000 – 10 000 are caesarean deliveries. The majority of caesarean deliveries performed are emergencies.

4.5 Ethical considerations

Approval to conduct the study will be obtained from the Human Research Ethics Committee (Medical) and the Graduate Studies Committee of the University of the Witwatersrand. Permission to collect data at CHBAH will be requested from the CHBAH Medical Advisory Committee (Appendix B). Approval was obtained from the Head of Department of Anaesthesiology at CHBAH (Appendix C). The study will be registered with the National Health Research Database as well as the Pan African Clinical Trials Registry.

Anaesthetists who meet the inclusion criteria will be approached. The study will be explained to them and they will be invited to take part. They will be given an anaesthetist information letter (Appendix D) and asked to sign an anaesthetist consent form (Appendix E) if they agree.

If the anaesthetist gives consent, patients awaiting theatre will be approached to assess whether they meet the inclusion criteria. In those who meet the inclusion criteria, the study will be explained and they will be invited to take part. They will be given a patient information letter (Appendix F) and asked to sign the patient consent form (Appendix G) if they agree.

The anaesthetist performing the spinal block will be known to the researcher and therefore not anonymous. However, there will be no link between the anaesthetist and the data collected. No anaesthetist will be included more than twice in the study. Patient data will be collected without identifying information, using a study number on a data collection form (Appendix H). A list with names, hospital numbers, date of surgery, anaesthetist performing the spinal block and study numbers will be compiled and kept on a separate patient personal details form (Appendix I). This form will be filed separately on a password-protected database. Confidentiality will be ensured as only the researcher and supervisors will have access to the raw data. The raw data sheets will be stored in a locked cupboard for six years after completion of the study.

Surgery must not be unreasonably delayed by inclusion in the study. If initiation into the study or completion of the study protocol would result in any delay in

taking the patient to the theatre, it will be abandoned and the patient excluded from the study.

If a patient withholds or withdraws consent after the study is explained to them, they may request to have an ultrasound-assisted technique.

In the landmark-based group, if an anaesthetist exceeds the maximum allowable number of needle passes, 21, the researcher will offer information from the preprocedural ultrasound. This is to reduce patient harm from randomisation into the landmark-based group. This ensures that no parturient is exposed to an excessive number of needle passes required for a spinal block. Information gained from the ultrasound may help the anaesthetist perform the spinal block, and withholding it would be unethical in cases where a high number of needle passes has been reached. The procedure would be deemed unsuccessful and the information excluded. Another patient would subsequently be recruited into this group to replace the exclusion.

The study will be conducted according to the principles of the Declaration of Helsinki (42) and the South African Guidelines for Good Clinical Practice (43).

4.6 Research methodology

4.6.1 Research design

A prospective comparative contextual study design will be used.

A prospective study is one in which an outcome is measured at the time it occurs in the specific population (44). In this study, the prospective measure will be data collected as the study takes place.

A comparative design is one in which a differing technique is implemented, and the effects of that technique on dependent variables are determined by comparison to a sample that did not receive that technique (44). In this study, the technique will be to have visible markings made on the patient's back using information gained from the preprocedural ultrasound. The landmark-based group will not have visible markings made.

A contextual design involves the use of a specific population (44). In this study, the specific population will be patients awaiting emergency caesarean delivery at CHBAH.

4.6.2 Study population

The study population will consist of patients awaiting emergency caesarean delivery at the CHBAH obstetric theatre complex.

4.6.3 Study sample

Sample size

The primary end-point was first-pass success rate. The sample size was determined in consultation with a biostatistician using Stata 14.2 (StataCorp, USA) software a sample size of 18 successful spinal blocks per group was needed. The calculation was based on first-pass success rate in the ultrasound-assisted group was 92% and in the landmark-based group was 44% in a study by Sahin et al. (45), giving a power of 90% and an alpha of 0.05.

Sampling method

In this study, a convenience sampling method will be used. Once patients are enrolled, they will be randomised into two groups, the ultrasound-assisted and the landmark-based group, using a simple randomisation chart (Appendix J).

Convenience sampling is the non-random use of the most easily accessible individuals in the sample population (44). Convenience sampling will be used because the researcher needs to perform the clinical assessment and ultrasound evaluation for all patients, as well as record technical measures of spinal block performance. The researcher's availability will be determined by the clinical schedule of the CHBAH Department of Anaesthesiology, and will include scheduled day shifts, scheduled night shifts, and non-clinical research time.

Randomisation is the assignment of participants to study groups based on chance alone (44). The randomisation chart was generated from an online randomisation

program (46). At randomisation, an envelope containing a number will be picked from a box. The number in the envelope will indicate which group the patient is assigned to, according to the randomisation chart (Appendix J). The envelope and number will only be returned to the box if the patient withdraws or is excluded from the study.

Inclusion and exclusion criteria

The anaesthetist inclusion criteria in this study are:

- qualified doctor working in the Department of Anaesthesiology
- medical officer or registrar
- with at least two years of supervised experience in anaesthesia
- who consents to inclusion to the study.

The anaesthetist exclusion criterion in this study is prior inclusion in the study two times.

The patient inclusion criteria in this study are:

- ASA I, II and III patients
- age $\geq$ 18 years
- presenting for emergency caesarean delivery
- who consent to take part in the study
- BMI at first antenatal weight recording $\geq 30 kg.m^{-2}$
- under spinal block as the first choice of anaesthetic
- by an anaesthetist who meets study criteria.

The patient exclusion criteria in this study are:

- contraindications to spinal block, including known spinal disease
- unable to communicate in English
- inability to adequately visualise structures during ultrasound scanning protocol
- exceeded maximum allowable number of needle passes during spinal block
- spinal block failure following procedure.

4.6.4 Data collection

Data collection sheet

A draft data collection sheet was constructed based on the literature review ensuring content validity. This was reviewed by three senior anaesthesiologists with an interest in obstetric anaesthesiology, ensuring content and face validity. After incorporation of feedback, the final data collection sheet (Appendix H) was generated. The sheet will capture the following information:

- patient characteristics
- assessment of spinal block difficulty
- ultrasound assessment
- randomisation
- technical measures of spinal block performance.

Data collection process

The data collection process is summarised in Figure 4.1.

Anaesthetist enrolment will involve confirming anaesthetist eligibility, verbally explaining the study and obtaining written informed consent. No anaesthetist will be included more than twice in the study, in order to prevent over-representation of any single individual anaesthetist's ability with regards to spinal anaesthesia.

Patient enrolment will occur in the CHBAH obstetric theatre complex. Within the obstetric theatre complex, patients are routinely brought to the patient receiving area prior to a theatre becoming available. This is done in order to minimise delays between operations. On average, patients wait between 35 – 50 minutes from their time of arrival in the theatre area to being taken into theatre for their procedure. This time will be used as an opportunity for enrolment. The patient's study eligibility will be checked, the study explained, the patient information letter and patient consent form offered.

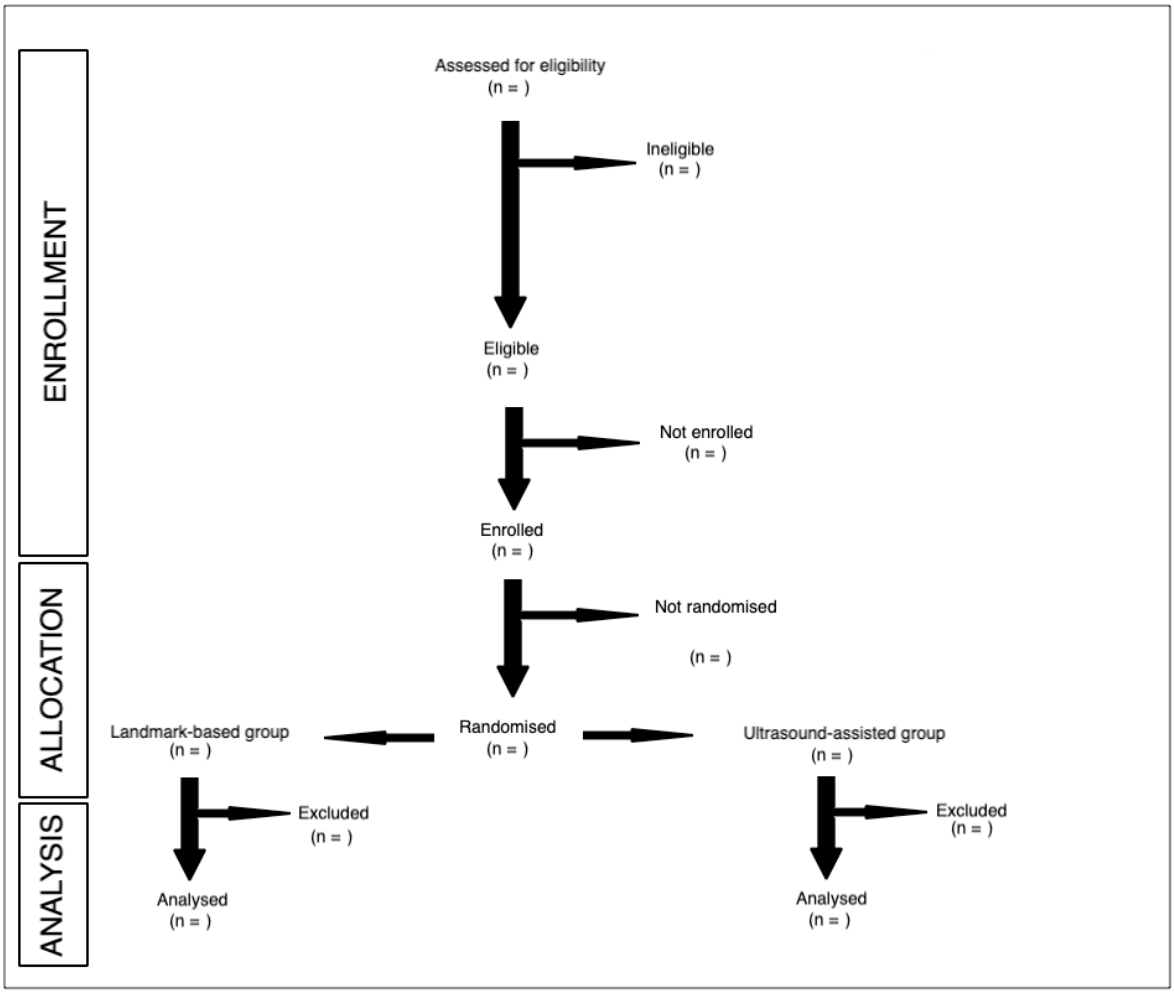


Figure 4.1 CONSORT flow diagram

If a patient withholds or withdraws consent after the study is explained to them, they may request to have an ultrasound-assisted technique. This will be done as per the study ultrasound-assisted group, but without inclusion in the study.

If a patient is enrolled, patient information will be recorded on the patient personal details form (Appendix I) and they will be assigned a study number. The study number will be used on the data collection sheet (Appendix H). Patient assessment will follow in three stages as per the data collection process flowchart. This will be done in a private part of the theatre complex waiting area with a screen, as per the local protocol for other procedures requiring privacy.

First, patient characteristics will be captured following a patient file review. Weight from the first recorded antenatal weight will be used. Height from the antenatal

notes will be used. If no height is recorded, a measuring tape will be used to determine height from head to heal while the patient is in the supine.

Second, the clinical assessment of spinal block difficulty will be done. This involves positioning the patient in a standardised manner. The sitting position recommended by the South African National Department of Health (39) will be used. They will sit with their legs over the side of the stretcher, with elbows resting on their knees, maximum flexion of the back and relaxed shoulders (39). This will also be demonstrated to them through the use of a drawing available both outside and inside the obstetric theatres. Upon adequate positioning, the patient's back flexion and ability to palpate spinal landmarks will be graded according to the factors associated with difficult spinal block. These findings will be used to categorise a patient as either having presence or absence of factors associated with a difficult spinal block.

The third stage of the patient assessment will consist of an ultrasound-based assessment of anatomical structures of the back. Marks on the patient's skin will be made using an 8280 Special Securitas UV Marker (Edding, Germany). A C1-5 curvilinear ultrasound probe will be used with a GE Logiq e ultrasound machine (GE, USA). The ultrasound scanning protocol is outlined in Appendix K, and is adapted from previous similar studies (31, 45). The probe will first be positioned in an oblique parasagittal orientation near the gluteal fold, and then the hyperechoic lines that indicate the sacrum and vertebral laminae will be identified. The probe will be moved in a cranial direction, with successive intervertebral spaces identified until the L2/3 space is reached. The midpoints of the L4/L5, L3/4 and L2/3 spaces will be marked with horizontal lines after identification of the best image that includes the anterior complex (anterior dura mater, posterior longitudinal ligament and body of the vertebra) and the posterior complex (posterior dura mater, epidural space and ligamentum flavum). The ultrasound distance will be measured at each interspace and recorded. The probe will then be turned to a transverse orientation and the midline of L3/4 identified. The midline will be marked with a vertical line above the probe. The probe will be tilted in the L3/4 space to obtain the best view of the anterior and posterior complexes, and the angle between the probe and the skin will be noted and marked to indicate needle angle of entry. The

points at which the vertical and horizontal lines would meet will indicate the needle entry points for each intervertebral space. The L4/5 space will be assessed for the midline and angle of entry as well, but will only be marked if either is significantly different from the L3/4 intervertebral space. If the ultrasound cannot be performed to adequately obtain all of the above information, the patient will be excluded from the study.

Following the completion of the patient assessment stage, randomisation of patients will be done. A patient randomised to the ultrasound-assisted group will have the invisible ink marked over with a visible Accura Permanent Marker (Claro, India) pen. A ZA-490 UV Flashlight, 9 LED (Zartek, South Africa) ultraviolet flashlight will be used to show the invisible ink whilst this is done. A patient randomised to the landmark-based group will have only the invisible ink marks, which will remain unseen by the anaesthetist performing the spinal block.

Following this, the patient will receive a spinal block as per national guidelines (39) after a theatre becomes available. The spinal block will be administered by the enrolled anaesthetist. Technical measures of spinal block performance will be assessed and recorded on the data collection sheet (Appendix H) by the researcher, who will be present in the theatre but will not interfere with the anaesthetic. Number of needle punctures, number of needle passes and intervertebral spaces entered will be counted by the researcher. Time will be measured in seconds (to the nearest second) using a stopwatch. If the patient is in the landmark-based group, the initial and final intervertebral spaces entered will be assessed by the researcher with the ultraviolet light upon completion of the procedure. Prior to needle withdrawal, the distance from the skin to the back of the needle hub will be measured with a ruler. This value will be subtracted from the total needle length (needle tip to back of hub) to determine the actual depth. The total needle length will be measured with a ruler after the spinal needle is taken out of the patient's back prior to disposal.

If an anaesthetist reaches the maximum allowable number of needle passes in a patient randomised to the landmark-based group, the information from the ultrasound assessment will be made available for their use. If an anaesthetist ultimately fails to reach the subarachnoid space to administer the anaesthetic, the

spinal will be considered failed. In both of these instances, the patient will be excluded and the procedure considered unsuccessful.

4.6.5 Data analysis

A REDCap® database will be used to capture data from completed data collection sheets. Data will be analysed in consultation with a biostatistician using the statistical program STATA version 14.2 (StataCorp, USA). Categorical variables will be described using numbers and percentages. Continuous variables will be described using means and standard deviations if normally distributed, or alternatively medians and ranges or interquartile ranges, as appropriate. The technical measures of spinal block performance (first-pass success rate, number of needle punctures, number of needle passes, procedure time) will be compared between the groups using the independent t-test or the Mann-Whitney U-test. Comparisons of patient factors (presence/absence of factors associated with difficult spinal block) with technical measures of spinal block performance will be made using a Fisher's exact test.. A p-value of 0.05 or less will be considered statistically significant. Correlation between UD and AD will be calculated using Peason's Correlation Coefficient, and reported with a 95% confidence interval.

4.7 Significance of the study

In the context of anaesthesia for emergency caesarean deliveries, any reduction in procedure time has the potential to improve outcomes (47, 48). Although the anaesthetic procedure is only a single component of the decision-to-delivery time that correlates with foetal outcome, in patients with a difficult spinal, it can be a avoidable source of delay (38). Any procedure that could be done preoperatively to improve technical measures of spinal block performance might, therefore, have significant benefit in our setting.

An ultrasound-assisted technique has been shown to improve first-pass success and decrease procedure time, particularly in patients at risk for a difficult spinal block (32). At CHBAH, patients booked for emergency caesarean delivery commonly wait 35 – 50 minutes before being taken into theatre. This period presents an opportunity to assess patients who may be at risk for a difficult spinal

block. A preprocedural ultrasound of the spine could improve technical performance of the spinal block without any delay in care. This has the potential to decrease anaesthetic and theatre time, reduce spinal failure rate, and decrease the overall risk to both the patient and the foetus.

4.8 Validity and reliability of the study

The validity of a study refers to the ability of the study to measure what it was designed to measure and reliability refers to the consistency of the results obtained (49). The validity and reliability of the study will be ensured through:

- using an appropriate study design
- standardised data collection sheet with face and content validity
- sample size determined in consultation with biostatistician
- researcher accredited and experienced in performing ultrasound-assisted procedures
- researcher will perform all the patient assessments and preprocedural ultrasounds using the same ultrasound machine, and will observe all the anaesthetists performing the spinal blocks
- data will be analysed in consultation with a biostatistician.

4.9 Potential limitations

The contextual study design may limit generalisability of the study results to other populations.

Convenience sampling may not adequately represent all emergency obstetric patients awaiting caesarean delivery.

A BMI measured at first antenatal visit may not be a true representation of the patient's body habitus at presentation for emergency caesarean delivery, and this may limit comparability.

4.10 Project outline

4.10.1 Time frame

Activity	Jan – May 2019	Jun 2019	Jul – Oct 2019	Nov 2019 – Mar 2020	Apr 2020	May 2020	Jun 2020	Jul 2020	Aug 2020	Sep – Oct 2020
Proposal preparation										
Literature review										
Proposal submission										
Ethics approval										
Postgraduate approval										
Data collection										
Data analysis										
Draft article										
Submission										

4.10.2 Budget

Item	Price per item (R)	Number of pages/items	Copies	Total (R)
Proposal	1.00	34	10	340.00
Postgraduate form	1.00	2	10	20.00
Anaesthetist information letter	1.00	2	50	100.00
Anaesthetist consent form	1.00	1	50	50.00
Patient information letter	1.00	2	50	100.00
Patient consent form	1.00	1	50	50.00
Data collection sheet	1.00	1	50	50.00
Patient personal details forms	1.00	2	1	2.00
Complete report	1.00	100	1	100.00
Edding invisible marker pens	57.50	3		172.50
Claro permanent marker pens	10.00	3		30.00
Zartek UV flashlight	199.00	1		199.00
Grand total				**R 1213.50**

The Department of Anaesthesiology will incur the costs of paper and printing for the postgraduate application, the patient and anaesthetist information and consent forms, the data collection sheets and patient personal details forms. The invisible marker pens, visible marker pens, ultraviolet flashlight and complete report will be funded by the researcher. The ultrasound machine used is the property of the Department of Anaesthesiology.

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4.12 Appendices

Appendix A – Factors associated with difficult spinal block

Factors associated with difficult spinal block tables

Table 1 – Grading of back flexion

Description	Grade	Factor present or absent
Convex curvature of spine	1	Absent
No/minimal spinal curvature	2	Present
Concave curvature of spine	3	Present

Table 2 – Grading of ability to palpate spinal landmarks

Description	Grade	Factor present or absent
Easily palpable/visible	1	Absent
Palpable but not visible	2	Absent
Poorly palpable	3	Present
Impalpable	4	Present

Appendix B – Letter to CHBAH Medical Advisory Committee

Dr Bojan Korda
Department of Anaesthesiology
University of the Witwatersrand
drbkorda@gmail.com
+27 78 228 3474

31 May 2019

Dear CHBAH Medical Advisory Committee

RE: MMed (Anaesthesiology) Research Site Permission

I am a registrar in the Department of Anaesthesiology. I am conducting a study as part of my Master of Medicine in Anaesthesiology, which is titled: Ultrasound-assisted versus landmark-based spinal block performance in emergency caesarean deliveries in obese patients at a central hospital.

The study will include obstetric patients awaiting emergency caesarean delivery in the CHBAH obstetric theatre complex. I will be studying whether the use of preprocedural spinal ultrasound improves efficiency in performing spinal blocks. All patients will receive standard care and no delay in patient care will result from inclusion into the study.

The study has received ethics approval from the Human Ethics Research Committee (Medical) of the University of the Witwatersrand (approval number _____).

The study will not result in additional cost to the hospital.

I hereby request permission to conduct research at Chris Hani Baragwanath Academic Hospital between October 2019 and March 2020. The length of time may be extended if the minimum number of participants have not been recruited in the initial six months.

I have attached the proposal. Please do not hesitate to contact me for further information.

Thanking you in advance

Yours truly,
Dr Bojan Korda

MP0777951
Registrar – Anaesthesiology
MBBCh (Wits), DipPEC (SA), DA (SA)

Appendix C – Approval from head of Department of Anaesthesiology at CHBAH

Dr Bojan Korda
Department of Anaesthesiology
University of the Witwatersrand
drbkorda@gmail.com
+27 78 228 3474

31 May 2019

Attn: Dr D Lines – Clinical Head CHBAH Department of Anaesthesiology

RE: MMed (Anaesthesiology) Research Site Permission

Dear Dr Lines

I am a registrar in the Department of Anaesthesiology. I am conducting a study as part of my Master of Medicine in Anaesthesiology, which is titled: Ultrasound-assisted versus landmark-based spinal block performance in emergency caesarean delivery in obese patients at a central hospital.

The study will include obstetric patients awaiting emergency caesarean delivery in the CHBAH obstetric theatre complex. I will be studying whether the use of preprocedural spinal ultrasound improves efficiency in performing spinal blocks. All patients will receive standard care and no delay in patient care will result from inclusion into the study.

The study will apply for ethics approval from the Human Ethics Research Committee (Medical) of the University of the Witwatersrand.

The study will not result in additional cost to the hospital. The use of one of the departmental ultrasound machines will be required during data collection.

I hereby request permission to conduct research in your department at Chris Hani Baragwanath Academic Hospital between October 2019 and March 2020. The length of time may be extended if the minimum number of participants have not been recruited in the initial six months.

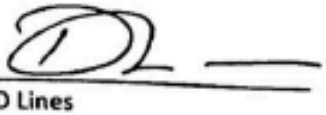
I have attached the proposal. Please do not hesitate to contact me for further information.

Thanking you in advance

Yours truly,
Dr Bojan Korda

Registrar – Anaesthesiology
MBBCh (Wits), DipPEC (SA), DA (SA)

Approved / Declined



Dr D Lines
Head: Clinical unit - Anaesthesiology
Chris Hani Baragwanath Academic Hospital

Appendix D – Anaesthetist information letter

Anaesthetist information letter for research: Ultrasound-assisted versus landmark-based spinal block performance in emergency caesarean delivery in obese patients at a central hospital

Hello, my name is Bojan Korda. I am a registrar studying at the University of the Witwatersrand to become an anaesthesiologist. Part of my studies involves completing a research project for a Masters of Medicine in Anaesthesiology. The title of my research project is "Ultrasound-assisted versus landmark-based spinal block performance in emergency caesarean delivery in obese patients at a central hospital".

A spinal block is the most commonly used anaesthetic technique used for anaesthesia during caesarean delivery. The technique practiced by the majority of anaesthetists involves the use of surface landmarks to identify the spinal needle entry point at the L3/4 intervertebral space. A recent alternative to this landmark-based technique involves the use of point-of care ultrasound of the spine. An ultrasound-assisted technique has been shown to improve entry point identification. It also provides accurate information about the depth of the subarachnoid space and the angle at which the needle should be advanced.

In this study I want to assess whether preprocedural ultrasound of the spine can assist an anaesthetist to improve the efficiency of performing a spinal block. Similar studies have been performed in obstetric patients in other settings, but no study could be found that looked at women of African ethnicity, nor in patients undergoing emergency caesarean delivery.

I would like to invite you to take part in this study. If you agree to take part in the study, I will ask you to sign a consent form for participation. If you are included in the study, I will approach patients that are waiting for emergency caesarean delivery who may come to your theatre. After obtaining their informed consent, a patient's back will be assessed clinically and with an ultrasound. During the ultrasound assessment, marks will be on the back. Information about how deep and at what angle the needle must be advanced will be recorded. The marks will be made using an "invisible" ink.

After the scan is completed, the patient will then be randomised. If they are randomised to the intervention group, the marks will be drawn over with a visible marker and the information regarding depth and angle shared with the patient's anaesthetist. In the control group the patient will receive routine care. All this will happen prior to your theatre becoming available for the patient's use and likely prior to any interaction between you and the patient. If the theatre becomes available whilst the patient is still getting assessed as part of the study, they will be then be excluded from the study. This is to ensure no delay in patient care occurs as a result of study inclusion.

Your anaesthetic plan should not be affected by inclusion into the study. Each included patient must receive standard care, and no decision should be made based on their inclusion or their randomisation. If a spinal block is the anaesthetic technique chosen by you, then I will be present in theatre to record certain aspects of how you perform the procedure. If the patient is in the intervention group, the skin marks and information provided can be used to guide your technique. I will explain what the marks made on the

patient's back indicate. If the patient is in the control group, the procedure should be performed as per your standard landmark-based technique. At the point at which you complete injecting through the spinal needle, a ruler will be used to measure the needle length at the skin prior to needle withdrawal. This will be to measure the needle depth used to reach the intrathecal space. Once the spinal block procedure is completed, I will leave the theatre and the data collection for the study will be completed. If the number of needle passes exceeds ten in a patient in the control group, the information from the ultrasound assessment will be offered to assist you.

As no anaesthetist may be overrepresented in the study, you can only be recruited to be involved in the study a maximum of two times. Therefore, a separate record of your inclusion will be kept but will not be used for any aspect of data analysis. No identifying information regarding your involvement in the study will be recorded on the data collection sheet. Your choice regarding involvement in the study will thus be kept confidential.

It is entirely your decision to be part of the study. You can also withdraw participation at any time. If you choose not to take part or to withdraw, you will not be prejudiced in any way by either myself or the Department of Anaesthesiology. The only direct benefit to participation in the study is the that additional information gained from the preprocedural ultrasound could add an extra layer of safety the spinal is very difficult. An indirect benefit of the study could be that patient care might improve as a result of findings from the study. There are no known risks associated with participation in the study.

If you have any questions please ask myself or Dr Dorinka Nel. You may contact me on 078 228 3474 or Dr Nel on #6367.

The study has been approved by the Human Research Ethics Committee (Medical) and the Graduate Studies Committee of the University of the Witwatersrand. You contact the Chairperson of the Ethics Committee (Professor C Penny) on 011 717 2301 or Clement.Penny@wits.ac.za. You may contact any of Human Research Ethics Committee (Medical) Administrative Officers on 011 717 1234/2656/2700 or any of the following emails: Zanele.Ndlovi@wits.ac.za, Rhulani.Mkansi@wits.ac.za, Charmaine.Khumalo@wits.ac.za, Josh.Ndlangamandla@wits.ac.za.
The ethics approval number is _____.

Thank you for your time. Please keep this letter in your records for reference purposes. The results of the study will be presented at a departmental meeting after the completion of the study report. If you would like to be informed regarding when this will occur, please let me know by contacting me on 078 228 3474.

Kind regards
Dr Bojan Korda

Appendix E – Anaesthetist consent form

Anaesthetist consent to participate in research study: Ultrasound-assisted versus landmark-based spinal block performance in emergency caesarean delivery in obese patients at a central hospital

I _____ the anaesthetist have been counselled and understand the study. I consent to participate in the study. I have read and understand the information sheet. All my questions have been answered. I understand that my identity will be protected at all times. I know that I may withdraw from the study at any time without prejudice towards myself.

_____	_____
Name of anaesthetist	Signature of anaesthetist
_____	_____
Name of researcher	Signature of researcher

Date:_____

Appendix F – Patient information letter

Patient information letter for research: Ultrasound-assisted versus landmark-based spinal block performance in emergency caesarean delivery in obese patients at a central hospital

Hello, my name is Bojan Korda. I am a doctor studying at the University of the Witwatersrand in Johannesburg to become a specialist anaesthetist. An anaesthetist is a doctor that takes care of patients and makes sure they don't feel pain during the operation. They either make the patient sleep or give them an injection to take pain away but still be awake.

Part of my studies requires that I do a research project. Research is a process used in seeking new knowledge. The title of my research project is "Ultrasound-assisted versus landmark-based spinal block performance in emergency caesarean delivery in obese patients at a central hospital".

When you have a caesarean delivery, an anaesthetist wants to make sure you have no pain. The way this is generally done is by doing something known as a 'spinal block'. A spinal block is done by placing a needle into the lower back, and putting medicine there to stop the patient feeling pain. After this starts to work, the surgeon can do the operation without the patient feeling pain. A spinal block is the safest way that an anaesthesiologist can block pain during this kind of operation. It is recommended by the South African government for this purpose, unless certain conditions exist that make a spinal block unsafe.

When inserting the spinal block the anaesthetist will show you a picture explaining how to sit. They will then feel your sides and back so they can know where to place the needle. They will give you a small injection first so that you do not feel them putting the spinal needle into your back. Most times they manage to do the spinal block easily, but in some patients the injection is more difficult. Each patient is different and it is difficult to know who it will be harder for.

Anaesthetic doctors sometime use ultrasound to 'see' underneath the skin in order to find out exactly where they must put the needle. Ultrasound machines use special ways to see what is happening underneath the skin without hurting the person. This is often done and has been shown to help find the right place to put the needle. Ultrasound of the spine has no known risks to either you or your baby.

The purpose of this study is to provide information about whether using ultrasound to make marks on the back before going into the operating room will help make it easier for the anaesthetist to do the injection.

I would like to invite to participate in my research project. Patients who participate will all have an ultrasound of the back with marks made that cannot be seen under a special light is used. Some patients will then have those areas made visible using a black marker pen on their skin, whilst others will have no further marks made. When the patient goes to the operating room, they will be treated in the same way regardless of which group they are in. The anaesthetic doctor will be able to see the markings in the visible pen group only. As the researcher, I will be in room taking notes but will not change how the spinal block is done.

After the spinal block is done, I may leave the operating room. The marks on the skin will wash off normally after a few days and are not harmful.

It is entirely your decision to be part of the study. You can also withdraw participation at any time. Even if you do not participate in the study you will receive usual care and no doctor, nurse or other staff member will be upset with you. You will not be paid to take part in the study. The only benefit to you in taking part in the study is that ultrasound of your back might make it easier for your anaesthetist to do your spinal. Another benefit to taking part is that the research could show us how to take better care of patients in the future. There are no known risks to taking part in the study.

If you agree to take part in the study, I will ask you to sign a consent form. This is a form of proof that you are happy to take part in the study. If you sign, I will ask you some questions, and will take you to a private area to examine your back. I will then do the ultrasound and use a pen to make marks. You will be sitting in the same position as for when you have the spinal block done in the operating room. The whole process will take about 15-20 minutes. If the operating room becomes available in that time, we will immediately stop the study so as to not delay your operation in any way. Your information will not be shared with anyone who is not involved in the research. No one will be able to tell that you were involved in this study when we show the results.

If you have any questions please ask myself, the other doctors or nurses. You may contact me on 011 933 9335.

The study has been approved by the Human Research Ethics Committee (Medical) and the Graduate Studies Committee of the University of the Witwatersrand. You contact the Chairperson of the Ethics Committee (Professor C Penny) on 011 717 2301 or Clement.Penny@wits.ac.za. You may contact any of Human Research Ethics Committee (Medical) Administrative Officers on 011 717 1234/2656/2700 or any of the following emails: Zanele.Ndlovi@wits.ac.za, Rhulani.Mkansi@wits.ac.za, Charmaine.Khumalo@wits.ac.za, Josh.Ndlangamandla@wits.ac.za.
The ethics approval number is _____.

Thank you for your time. Please keep this letter with you so that you are able to see any of the information above in the future if you want to. If you would like us to share the results with you after they are released, you can contact me on 011 933 9335.

Kind regards,
Dr Bojan Korda

Appendix G – Patient consent form

Patient consent to participate in research study: Ultrasound-assisted versus landmark-based spinal block performance in emergency caesarean section in obese patients at a central hospital

I _____ the patient have been counselled and understand the study. I consent to participate in the study. I have read and understand the information sheet. All my questions have been answered. I understand that my identity will be protected and concealed at all times. I understand that participation in the study will not harm me. I know that I may withdraw from the study at any time without anyone being upset. I know that I will not be paid to participate in the study.

_____	_____
Name of patient	Signature of patient
_____	_____
Name of researcher	Signature of researcher
_____	_____
Name of witness	Signature of witness

Date:_____

Appendix H – Data collection sheet

Data collection sheet Study no:_____

Patient characteristics

Time at study initiation (HH:MM)		:	
Indication for caesarean delivery		Weeks gestation (weeks completed)	
Gravidity	Parity	Age (years)	
Height (cm)		Weight (kg)	

Clinical assessment of spinal block difficulty

Time at clinical assessment (HH:MM)	:

Back flexion grade (circle)

Concave	Straight	Convex

Palpation grade (circle)

Easily palpable/visible	Not visible but palpable	Poorly/vaguely palpable	Impalpable

Ultrasound assessment

Start time (HH:MM)	:
L4/5 ultrasound depth (mm)	
L3/4 ultrasound depth (mm)	
L2/3 ultrasound depth (mm)	
Angle to best view L3/4 (degrees to nearest 10°)	
Angle to best view L4/5 (degrees to nearest 10°)	
End time (HH:MM)	:
Adequate ultrasound views (circle)	Y N

Randomisation *(place tick next to group randomized to)* RANDOMISATION NUMBER:

Ultrasound-assisted group	Landmark-based group

Technical measures of spinal block performance

Spinal procedure start time (HH:MM:SS)	
Number of needle punctures	
Number of needle passes	
Number of intervertebral spaces attempted	
Initial intervertebral space	
Final intervertebral space	
Skin to needle hub distance (mm)	
Total needle length (mm)	
Needle depth (mm)	
Spinal procedure end time (HH:MM:SS)	:
Procedure time (s)	

Appendix I – Patient personal details forms

Patient personal details form 1

First name	Surname	Middle names	Hospital no	Date of surgery DD/MM/YY	Anaesthetist	Study no
				/ /		1
				/ /		2
				/ /		3
				/ /		4
				/ /		5
				/ /		6
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				/ /		24
				/ /		25

Patient personal details form 2

First name	Surname	Middle names	Hospital no	Date of surgery DD/MM/YY	Anaesthetist	Study no
				/ /		26
				/ /		27
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				/ /		49
				/ /		50

Appendix J – Randomisation sheet

Randomisation chart

RANDOM NUMBER	GROUP
30	A
33	A
16	A
20	A
24	A
3	A
36	A
25	A
18	A
12	A
11	A
27	A
5	A
14	A
22	A
32	A
35	A
31	A
34	B
23	B
29	B
21	B
26	B
8	B
13	B
15	B
2	B
28	B
4	B
9	B
7	B
17	B
19	B
1	B
10	B
6	B

SORTED RANDOM NUMBER	GROUP
1	B
2	B
3	A
4	B
5	A
6	B
7	B
8	B
9	B
10	B
11	A
12	A
13	B
14	A
15	B
16	A
17	B
18	A
19	B
20	A
21	B
22	A
23	B
24	A
25	A
26	B
27	A
28	B
29	B
30	A
31	A
32	A
33	A
34	B
35	A
36	A

Key:

Group A – Landmark-based group
Group B – Ultrasound-assisted group

Appendix K – Ultrasound scanning protocol

Ultrasound scanning protocol

Parasagittal oblique orientation
Sacral line, L5 lamina & L5/S1 identified
L4/5 identified
Anterior & posterior complex identified
Midpoint marked
Measure ultrasound depth (mm)
L3/4 identified
Anterior & posterior complex identified
Midpoint marked
Measure ultrasound depth (mm)
L2/3 identified
Anterior & posterior complex identified
Midpoint marked
Measure ultrasound depth (mm)
Transverse orientation at L3/4
Spinous process identified
Midpoint marked above & below
Tilt until anterior & posterior complex optimised
Measure angle to best view (degrees to nearest 10°)
Move to L4/5
Spinous process identified - If different from L3/4 - mark
Tilt until anterior & posterior complex optimised
Measure angle to best view (degrees to nearest 10°) - If different from L3/4 - mark

Section 5: Annexures

5.1 Letter of Approval – Chris Hani Baragwanath Academic Hospital Medical Advisory Committee

GAUTENG PROVINCE
REPUBLIC OF SOUTH AFRICA

MEDICAL ADVISORY COMMITTEE

CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

PERMISSION TO CONDUCT RESEARCH

Date: 22nd October 2019

TITLE OF PROJECT:

Ultrasound-assisted versus landmark-based spinal block performance in emergency causarean delivery in obese patients at a central hospital.

UNIVERSITY: Witswatersrand

Principal Investigator: Dr Bojan Korda

Department: Anaesthesiology

Supervisor : Dr Juan Scribante

Permission Head Department (where research conducted): Yes

The Medical Advisory Committee recommends that the said research be conducted at Chris Hani Baragwanath Academic Hospital. The CEO / management of Chris Hani Baragwanath Academic Hospital is accordingly informed and the study is subject to:-

- **Permission having been granted by the Committee for Research on Human Subjects of the University of the Witwatersrand.**
- The Hospital will not incur extra costs as a result of the research being conducted on its patients within the hospital
- The MAC will be informed of any serious adverse events as soon as they occur
- Permission is granted for the duration of the Ethics Committee Approval.

Recommended
(On behalf of the MAC)
Date: 22/10/2019

Approved/~~Not Approved~~
Hospital Management
Date: 25/10/2019

5.2 Ethics approval

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R14/49 Dr Bojan Korda

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M190614 MED19-05-126

NAME: (Principal Investigator)	Dr Bojan Korda
DEPARTMENT:	Anaesthesiology Chris Hani Baragwanath Academic Hospital
PROJECT TITLE:	Ultrasound-assisted versus landmark-based spinal block performance in emergency caesarean delivery in obese patients at a central hospital
DATE CONSIDERED:	28/06/2019
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Helen Perrie, Juan Scribante and Dorinka Nel
APPROVED BY:	Dr C Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	08/11/2019

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 in Room 301, Third floor, Faculty of Health Sciences, Phillip 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 June and will therefore be due in the month of June each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature

09/11/2019
Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

5.3 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

13 November 2019
Person No: 0701001K
PAG

Dr B Korda
31 Cedarwood
1076 Conelius Street
Weltevredepark
1709
South Africa

Dear Dr Bojan Korda

Master of Medicine in Anaesthesia: Approval of Title

We have pleasure in advising that your proposal entitled *Ultrasound-assisted versus landmark-based spinal block performance in emergency caesarean delivery in obese patients at a central hospital* 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

5.4 National Health Research Database

Proposal Details: GP_201910_009

GAUTENG HEALTH RESEARCH COMMITTEE

APPLICATION DETAILS

TITLE OF RESEARCH PROJECT

Ultrasound-assisted versus landmark-based spinal block performance in emergency caesarean delivery in obese patients at a central hospital

TYPE OF STUDY

Academic

STATUS OF APPLICATION

Approved

STATUS OF PROJECT

On-Going

PROPOSAL SUBMISSION DATE

2019/10/04

5.5 Pan African Clinical Trials Registry

Pan African Clinical Trials Registry

South African Medical Research Council, South African Cochrane Centre
PO Box 19070, Tygerberg, 7505, South Africa
Telephone: +27 21 938 0506 / +27 21 938 0834 Fax: +27 21 938 0836
Email: pactradmin@mrc.ac.za Website: www.pactr.org

Trial no.:	PACTR202001800912516	**Date of Approval:**	07/01/2020
Trial Status:	Registered in accordance with WHO and ICMJE standards		

TRIAL DESCRIPTION	
Public title	Ultrasound-assisted versus landmark-based spinal block performance in emergency caesarean delivery in obese patients at a central hospital
Official scientific title	Ultrasound-assisted versus landmark-based spinal block performance in emergency caesarean delivery in obese patients at a central hospital
Brief summary describing the background and objectives of the trial	Introduction and Justification: Obstetric anaesthesia-associated mortality and morbidity has decreased dramatically over the past several decades. Complications of general anaesthesia remain a significant cause of maternal mortality, particularly in South Africa. Neuraxial anaesthesia would be a more appropriate technique in many of these cases. Difficult spinal anatomy is associated with obesity in pregnancy. Preprocedural ultrasound may assist in these cases. It has been shown to improve spinal block performance, decrease the number of attempts and reduce procedural time in this subpopulation. Aims: The aim of this study is to assess the effect of the ultrasound-assisted technique on the technical performance of spinal blockade by anaesthetists in emergency caesarean deliveries in obese patients at a central hospital, as compared to the standard landmark-based technique. The primary objectives of this study are to: • to describe and compare the first-pass success rate • to describe and compare the number of needle punctures • to describe and compare the number of needle passes • to describe and compare the procedure time in the ultrasound-assisted and landmark-based groups. The secondary objectives of this study are to: • describe the initial intervertebral space used, number of intervertebral spaces attempted and final intervertebral space used during spinal block in each group • describe the clinical assessment of factors associated with difficult spinal block in each group • compare patient factors (presence/absence of factors associated with difficult spinal block) with technical measures of spinal block performance • compare the measured ultrasound distance (UD) to the actual needle depth (ND).
Type of trial	RCT
Acronym (If the trial has an acronym then please provide)	
Disease(s) or condition(s) being studied	Anaesthesia
Sub-Disease(s) or condition(s) being studied	
Purpose of the trial	Ultrasound Assisted Spinal Anaesthetic
Anticipated trial start date	02/12/2019
Actual trial start date	03/01/2020
Anticipated date of last follow up	31/03/2020
Actual Last follow-up date	24/02/2020

5.6 Turnitin report

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ORIGINALITY REPORT

6%	4%	3%	1%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	www.dovepress.com Internet Source	1%
2	ses.library.usyd.edu.au Internet Source	1%
3	canjsurg.ca Internet Source	1%
4	Burhan Apiliogullari, Inci Kara, Seza Apiliogullari, Oguzhan Arun, Ali Saltali, Jale Bengi Celik. "Is a Neutral Head Position as Effective as Head Rotation During Landmark-Guided Internal Jugular Vein Cannulation? Results of a Randomized Controlled Clinical Trial", Journal of Cardiothoracic and Vascular Anesthesia, 2012	1%