Documentation of spinal anaesthesia technique and block level at caesarean section

by

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DECLARATION

I, *Dr Michiel Adriaan du Toit*, hereby declare that the work on which this dissertation is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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Heléne du Toit (mother) and René Grant (sister), without your support, encouragement and unwavering faith in me this would not have been possible. To my Dad, you are missed.

List of Abbreviations

CS	Caesarean section
SA	Spinal anaesthesia
MMH	Mowbray Maternity Hospital
LA	Local anaesthetic

Chapter 1: Review of the Literature

1. Objectives

The aim of the following narrative review is to examine the current evidence for and controversies surrounding documentation concerning- and testing of levels of spinal block at caesarean section. Details relating to sensory blockade following intrathecal local anaesthetic injection are discussed. The relevant data and expert reviews on documentation of sensory block following spinal anaesthesia (SA) are described. A review of the relevant, published medicolegal data is included.

2. Literature Search Strategy

All publications relevant to the subject were obtained online, from the University of Cape Town Health Science Library search facility. Publications were obtained from 14 medical digital archive databases worldwide. Literature published up to- and including the year 2020 was included. In total, 43 relevant publications were identified.

3. Quality Criteria

Keywords and phrases used in the search, in various combinations, included: “spinal anaesthesia”, “obstetric anaesthesia”, “spinal block testing”, “neuraxial block testing”, “failed spinal”, “anaesthesia litigation”, “obstetric anaesthesia litigation”.

4. Summary of the Literature

a. Introduction

Neuraxial anaesthesia has changed the landscape of obstetric anaesthesia. The ease of administration and relative safety have made spinal anaesthesia (SA) the preferred technique for elective and most emergency caesarean sections (CS).

Complications following SA may include incomplete sensory block, resulting in breakthrough pain. Pain during CS is a common reason for successful medicolegal claim. It has been stated by Russell that, “if a block fails in mid-surgery, even with cold or pinprick level at or above T4, and there is no assessment indicating an adequate level of block to touch preoperatively, then difficulties for the anaesthetist lie ahead should litigation ensue”.[1]

b. Litigation

In the UK, data from the National Health Service Litigation Authority (NHSLA) indicates that pain during CS under neuraxial anaesthesia is the commonest negligence claim against obstetric anaesthetists. During a ten-year period from 2000 to 2010, damages awarded for successful claims exceeded £19 million. This represents 3.8% of all successful obstetric claims (anaesthesia and non-anaesthesia related) to the NHSLA.[2] Furthermore a review article by Szypula et al. indicates that of the 366 claims related to regional anaesthesia and analgesia (both obstetric and non-obstetric), 63 (17%) were for inadequate block during CS and labour. This accounts for 31% of all obstetric anaesthetic related claims.[3] Further analyses of the NHSLA database indicate that in 42% of cases, surgery was allowed to start before a satisfactory sensory block was established. Furthermore, in 15% of cases the patient denied that any testing on the sensory block was carried out prior to skin incision.[2]

In the USA, data from the ASA Closed Claims Project (1990 – 2003), indicates that claims for maternal minor complications such as headache, back pain, pain during surgery and emotional stress represent 28% of obstetric anaesthetic claims.[4] Claims specifically for pain during CS were not reported. Data from the ASA closed claims project during the 1980s and 1990s indicated that 17% of all obstetric neuraxial anaesthesia claims were due to inadequate analgesia. This includes spinal and epidural anaesthesia during labour and CS.[5] The analysis of Chadwick et al of the ASA Closed Claims Project database revealed that pain during SA for CS accounts for 11% of all the obstetric anaesthesia - related claims.[6] The specific neuraxial technique was not specified. A central theme from these claims was the reluctance of the anaesthetist to accept block failure and convert to general anaesthesia.

c. Controversies surrounding testing of sensory modalities prior to SA

Joseph Erlanger and Herber Gasser were awarded the Nobel Prize in Medicine and Physiology in 1944 for their work on the “highly differentiated functions of a single nerve fiber”. To date, the Erlanger and Gasser classification is still widely used to determine specific functions of nerve fibers. According to this classification, to successfully block nociception the thinly myelinated Aδ fibers and the unmyelinated

C-fibers require blockade. Sensory testing relies on the other modalities that are also transmitted by these nerves:

(1) Aδ fibers: Pain, touch and cold sensation.

(2) C-fibers: Pain, warm sensation and some mechanoreception.

To obliterate any sensation of touch and pressure, the thickly myelinated Aβ fibers must also be blocked. Not all pelvic sensory nerves enter the spinal cord at their level of origin (T10 to L2), some travel in conjunction with sympathetic fibers to numerous sympathetic plexuses and only synapse with the spinal cord at considerably higher levels.[7] In normal neuronal conduction, depolarisation occurs when Na^+ channels open and the transmembrane potential becomes less negative. The predominant action of local anaesthetics is to block the Na^+ channels in neurones. In the presence of local anaesthetics, these Na^+ channels remain in the inactivated state and neuronal impulse conduction and propagation is halted.[8]

Some of the practical testing of the sensory block produced by SA has not changed much from the original description by Bier in 1899.[9] In his landmark publication he documented a variety of tests: "…sensual perception of needle pricks to the thigh, …strong pinching with dental forceps." Some testing modalities are not currently in use: "a small incision in the thigh, …application of a burning cigar, …a strong blow with an iron hammer against the tibia, vigorous blows with the knuckles against the tibia…"

By convention, three modalities are regularly used to test loss of sensation after SA, namely: cold, light touch and pinprick pain. It is assumed by most anaesthesia providers that a loss of sensation of these modalities predicts the effectiveness of SA in the provision of surgical anaesthesia. This is a common false assumption and breakthrough pain is still possible despite a loss of sensation of the above stimuli. The most likely reason for breakthrough pain during surgery, despite loss of sensation of other modalities, is that stimulation of cold, light touch and pinprick activates different pathways and nociceptors compared to surgical stimulation. Also, the intensity of the testing stimulus is significantly lower than surgical stimulation.[10] Therefore, no modality of testing can predict 100% effectiveness in blocking nociception during surgical stimulation. In an attempt to improve the predictive value

for surgical anaesthesia, more than one modality is used during testing. Other modalities like laser stimulation, electrical stimulation, chemical stimulation and evoked potentials have also been explored to improve the predictability of surgical anaesthesia under regional block. Most of these modalities are impractical, expensive and labour intensive, and therefore not routinely used except during nociception research.[10,11] Most general and obstetric anaesthesia textbooks do not specify what sensory modality should be used when performing testing before skin incision.[12] This indicates that there is currently no single gold standard.

After injection of local anaesthetic into the sub-arachnoid space there is a differential spread of the blockade of touch, cold and pinprick. Sensory blockade to light touch is lower than that to pinprick and cold. Furthermore, sensory blockade to touch is the last to be established and the first to regress after a single injection of local anaesthetic.[13] The *mean* difference between cold or pinprick and light touch sensation loss only differs by one to two dermatomes, but because of individual variability, this difference can be up to ten dermatomes.[14-19] Therefore, if a patient reports loss of sensation to cold, it cannot be assumed that the sensory block to touch is two dermatomes lower, and potentially adequate for surgical anaesthesia. Loss of sensation to touch *appears* to be the best predictor of adequate surgical anaesthesia, but has not been agreed upon by obstetric anaesthetists.[1,17,20,21] Due to wide individual variability, even apparently adequate blockade of the sensation of touch is unreliable to predict a pain-free operation.[22] Complicating the use of touch as a test modality, is the fact that the addition of opioids to the local anaesthetic can potentially decrease the dermatomal level required for surgical anaesthesia, as measured by blockade of sensation of touch. However, the extent of decrease is not predictable. [16,22-24]

Testing and documentation of sensory loss in response to specific testing modalities is constantly a source of confusion among anaesthetic providers. Firstly, the blockade of a testing modality is not 100% at one dermatome and 0% at the adjacent dermatome, since a transitional zone exists. The lower dermatomal level can be described as the “first touch level” and the upper dermatomal level can be described as the “touch same as the control stimulus” level. This transitional zone between “first touch” and “touch same as control stimulus” is about two dermatomal levels. Furthermore, in some patients this difference in dermatomal level increased over

time to as much as six dermatomes.[25] The use of “first touch” or “feeling something” level provides a better indication for adequate blockade before skin incision.[17,26] Secondly, Russell[27,28] has suggested that the dermatomal level required for surgical anaesthesia is a block level *up to (and including) T4*, or the *upper level of block is T5.* Some authors have adapted this specific wording, but most have not. Thus, the same block level might be recorded differently between individual anaesthetists.[18] The exact wording of the dermatome included (or excluded) is not usually stated in the literature and therefore some variations in interpretation will arise. Thirdly, inconsistency in the accurate identification of dermatomes among anaesthesia providers has been demonstrated by Congrave, et al[29] - only 68% of participants were able to correctly identify the T5 dermatomal level. More worrisome is that one in seven participants inaccurately indicated the T5 dermatomal level two or more dermatomes above or below. There also appeared no significant difference between consultants, registrars and senior house officers, with respect to the dermatomal levels recorded. The implication is that a lower or higher blockade level would be accepted with a potential subsequent increase either in intraoperative pain or cardiovascular and respiratory compromise.

d. Common testing modalities used in clinical practice

Commonly used modalities to test sensory loss have questionable efficacy and predictability. Unfortunately, other alternatives are expensive, and most are impractical for everyday clinical application.[10,11] Therefore, with no alternatives in the foreseeable future, reviews of different methods and devices to test the common modalities are a topic of considerable debate among obstetric anaesthetists.

Ethyl chloride is a commonly used to test sensory loss after SA. Ethyl chloride is kept as a liquid in a glass container with a valve at the top end allowing release of liquid on pressure. With slight pressure only droplets will be delivered, and if more pressure is applied to the valve the liquid will exit in the form of a spray. The cooling property of ethyl chloride is the result of an adiabatic process; as the gas expands, there is no heat exchange between the gas and the surroundings. The energy required to overcome its van der Waals forces, and change from a liquid to a gas, comes from the kinetic energy of the gas molecules themselves, resulting in cooling.[30]

Two modalities can be tested, namely cold and touch. Some confusion may arise between the anaesthesia provider and the patient when evaluating sensory loss, because the dermatomal level for loss of sensation of touch will be lower than for cold. Another consideration in the evaluation of sensation of touch, is that the force applied with ethyl chloride should be standardised. With careful administration of a drop, a single point stimulus may be applied. When more force is applied to the valve, and employing a greater distance to the skin, this becomes a multi-point stimulus; thus, not light touch, but pressure sensation is evaluated. In a low resource setting, ice packs or cubes may be used instead of ethyl chloride to test loss of cold sensation. Once again, multiple modalities may be tested if there is not careful standardisation, and confusion can arise.

An attractive alternative to the use of ethyl chloride in testing loss of touch sensation is the use of a Neuropen monofilament. This simple device is not flammable, has no pollution properties, can be reused, and consistently delivers a standardised force. A study by Walsh et al[31] indicates that a Neuropen monofilament and ethyl chloride have comparable efficacy when used to test loss of touch sensation. Another innovative method of testing loss of touch sensation is the use of a 25G pencil-point spinal needle with the stylet removed. The tip of the needle is placed in the tip of a 2 ml syringe and bent at a 90° angle. The needle is applied to the skin with enough downward force that the needle itself begins to bend. The force applied by the tip to the skin is comparable to the force applied by a monofilament. According to Seller et al[32], this effect is reproducible and comparable with the monofilament, but these findings have not been verified. This method can be used to evaluate loss of touch sensation and loss of pinprick. Again, confusion may arise between the patient and the anaesthetist about the specific modality that is evaluated, when differential zones are considered.

Warmth sensation has also been used for level testing. Heat receptors in the skin are activated between 37°C and 44°C. Thermal nociceptors are activated at skin temperatures above 45°C.[33] Warm air at a temperature of 40±0.2°C to test loss of sensation has proven equivocal to the use of ethyl chloride.[34]

When evaluating pinprick sensation or another nociceptive stimulus, like a pinch from a forceps by the obstetrician, care should be taken not to repeat the stimulus too frequently. With recurrent painful stimulation to a single location, temporal summation can occur. Temporal summation occurs when repetitive nociceptive stimuli is applied, with a resultant increase in pain perception. When a non-nociceptive stimulus follows, it may also be interpreted as painful.[11] Epidural bupivacaine and general anaesthesia with isoflurane will only attenuate temporal summation, while intrathecal bupivacaine completely inhibits temporal summation.[10,11]

e. Documentation of spinal level

Literature on the documentation of the adequacy of level of spinal block is sparce. Currently there are no clear published guidelines on the required documentation of spinal block testing before CS. The suggested block height required for surgical anaesthesia during CS has changed over the years. This level has varied from as low as T8 to the current accepted T4/5. In a UK national survey of the practice of obstetric anaesthesia, the majority of providers tested more than one modality, with cold being the most common modality.[35] In general, providers were satisfied if the sensory block to cold was T4, touch to T5, and pinprick to T4. Interestingly, the proportion of providers who tested no modality decreased significantly in the 2010 survey compared to the previous survey done in 2004. This could be a reflection of the medicolegal climate in the UK and the high incidence of successful litigation for pain during CS.[2,3] The above practice is not in keeping with current practice in South Africa. In a descriptive, observational cross-sectional study done in KwaZulu-Natal in 2016, only 56% of anaesthesia providers reported routine testing of the dermatomal level of SA and only 59% of specialists reported such testing. There was also a considerable discrepancy of opinion on which modality to use when testing block adequacy and on the required block level needed for pain-free surgery.[36] The above study reports on data in the form of questionnaires completed by correspondents and does not reflect actual documentation of block adequacy.

In an audit by Olateju et al[37] of obstetric anaesthesia records, the block height and quality of spinal block was evaluated before and after a lecture given on obstetric anaesthetic record keeping. Block height was poorly recorded both before the lecture (0%) and after the lecture (69%). The documentation of the quality of the block was

better recorded after the lecture (52% vs. 99%). No mention is made of the modality used to test the efficacy of SA. Audits on the quality of documentation during regional anaesthesia for caesarean section are listed in Table 1.[38-42]

f. Conclusions

Assessment of the dermatomal level of nerve block prior to SA for CS is controversial, both in terms of the levels required for surgical anaesthesia, and the best combination of modalities for testing. Adequate documentation of the details of practice of SA for CS, both in view of patient safety, and for the purposes of providing adequate information in the event of medical claims for inadequate anaesthesia, is of paramount importance. Therefore, the purpose of the present research audit, was to perform a retrospective assessment of such documentation by anaesthesia providers, on anaesthesia charts completed at a secondary level obstetrics hospital in Cape Town, South Africa.

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Table for narrative review

Table 3 – Documentation of specific aspects of spinal anaesthesia in published audits

Authors	Sensory dermatome level blocked (%)	Testing modality (%)	Laterality (%)	Intraoperative comfort (%)
Miu M[38]	72	71	57	20
Karuppudayar S[39]	87	58	NR	12
Kurup M[40]	87	54	NR	33
Gorton P[41]	85	NR	NR	63
Uppugonduri S[42]	75	53	45	3

Numbers indicate percentage of charts documenting the individual aspect of the practice of spinal anaesthesia; NR = not recorded.

Chapter 2: Manuscript

Title Page

Documentation of spinal anaesthesia technique and block level at caesarean section

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Abstract

Background

The ease of administration and relative safety of spinal anaesthesia has made this the preferred technique for elective and many emergency caesarean sections. Complications include incomplete sensory block, resulting in intraoperative breakthrough pain, which is commonly associated with a successful medicolegal claim. If documentation of spinal anaesthesia technique was found to be inadequate in the course of such medicolegal proceedings, it is likely that the decision would be against the anaesthetist. The purpose of this study was to evaluate documentation by anaesthetists relating to the establishment of surgical anaesthesia utilizing subarachnoid block.

Methods

A retrospective folder analysis was conducted at Mowbray Maternity Hospital in Cape Town, South Africa. One hundred consecutive spinal anaesthesia charts, each completed by a different anaesthetist, either a registrar or specialist, were analysed, starting December 31st, 2018, and proceeding retrospectively in time until the sample size was achieved.

Results

Of the 100 cases of spinal anaesthesia for caesarean section analysed, 68 were emergency and 32 elective operations. After literature review, 12 variables were identified requiring documentation, so that adequate information would be available in the event of medicolegal action. In 23% and 32% of patients respectively, 7 or 8/12 were recorded. Ninety percent of anaesthesia charts had inadequate documentation, defined as information on fewer than 10 of the specified variables.

Conclusion

The quality of documentation of procedure and block level during spinal anaesthesia for caesarean section was inadequate. National guidelines should be drafted and standardised to improve the quality of these records, both for quality of care and medicolegal purposes.

Introduction

The ease of administration and relative safety have made spinal anaesthesia (SA) the preferred technique for elective- and most emergency caesarean sections. Complications include incomplete sensory block, resulting in intraoperative breakthrough pain, which is commonly associated with a successful medicolegal claim. It has been stated by Russell that, “if a block fails in mid-surgery, even with cold or pinprick level at or above T4, and there is no assessment indicating an adequate level of block to touch preoperatively, then difficulties for the anaesthetist lie ahead should litigation ensue”.[1] In the UK, data from the National Health Service Litigation Authority (NHSLA) indicates that pain during caesarean section (CS) under neuraxial anaesthesia is the commonest negligence claim against obstetrics anaesthetists. During a ten-year period from 2000 to 2010, damages awarded for successful claims exceeded £19 million. This represented 3.8% of all successful obstetric claims (anaesthesia and non-anaesthesia related) to the NHSLA.[2] Furthermore, Szypula et al have reported that of the 366 claims related to regional anaesthesia and analgesia (both obstetric and non-obstetric), 63 (17%) were for inadequate block during CS and labour. This accounted for 31% of all obstetric anaesthesia-related claims.[3] Further analysis of the NHSLA database indicates that in 42% of cases, surgery was allowed to start before a satisfactory sensory block was established. Furthermore, in 15% of cases the patient denied that any testing of the sensory block was carried out prior to skin incision.[2]

From 1990 – 2003, claims for maternal minor complications like headache, back pain, pain during surgery and emotional stress represented 28% of the total for obstetric anaesthesia.[4] Unfortunately, data specifically regarding pain during caesarean section were not reported. In the USA, data from the ASA Closed Claims Project during the 1980s and 1990s indicated that 17% of all obstetric neuraxial anaesthesia claims were due to inadequate analgesia. This included spinal and epidural anaesthesia during labour and CS.[5] The analysis of Chadwick et al of the ASA Closed Claims Project database revealed that pain during anaesthesia for CS accounted for 11% of all the obstetric anaesthesia-related claims.[6] The specific neuraxial technique was not specified. A central theme from these claims was the

reluctance of the anaesthetist to accept block failure and convert to general anaesthesia.

The purpose of this study was to evaluate documentation relating to the establishment of surgical anaesthesia employing SA for CS. We hypothesised that documentation of SA for CS at Mowbray Maternity Hospital (MMH), a secondary-level facility in Cape Town, South Africa, is inadequate.

Methods

A retrospective folder analysis was conducted at MMH, after obtaining ethics approval from the Human Research Ethics Committee of the Faculty of Health Sciences of the University of Cape Town (HREC 409/2018). Women of all ages presenting for elective or urgent/emergency CS, under SA were included, whether or not supplementation with intravenous agents or conversion to general anaesthesia were subsequently required. The only exclusion criterion was missing anaesthesia notes. After consulting the theatre record books at MMH, 100 consecutive SA charts, each completed by a different anaesthetist, either a registrar or specialist, were analysed, starting on December 31st, 2018, and proceeding retrospectively until the sample size was achieved.

After a literature review, 12 variables that contribute to patient safety and comfort, were identified as requiring documentation. In addition, should medicolegal action arise, all of this information should be available:

1) Report of an aseptic technique.
2) Needle type, gauge and length.
3) Lumbar vertebral level at which the dura was punctured.
4) Number of passes of the needle at each level attempted.
5) Experience of paraesthesia.
6) Clear cerebrospinal fluid (CSF) flow after dural puncture.
7) Local anaesthetic and dose administered.
8) Opioid and dose administered.
9) Method used for testing the block.
10) Dermatomal level of sensory block.
11) Adequate surgical anaesthesia, or intervention if SA was inadequate, including unilateral block.
12) Documentation in recovery area of ability to lift the legs, or dermatomal level of sensory block.

In addition, the following information was also captured on the case report form:

- Degree of urgency of the CS.

- Date and time of anaesthetic.
- Level of experience of the anaesthesia provider.
- Patient age.
- Time intervals: SA to skin incision time; SA to uterine incision time; SA to skin closure.

Block height in the recovery area was initially measured by the anaesthetist, and subsequently by a nursing sister who had been adequately educated as to dermatomal levels for block height

The primary outcome was the proportion of anaesthesia records demonstrating inadequate documentation of required information, defined as <10/12 of the above variables. Secondary outcomes included a description of the proportion of records omitting a number of these factors. In addition, a comparison was made of the number of required variables documented by registrars and specialist anaesthetists.

Statistical analysis

Sample size calculation

The expected proportion of inadequate documentation of required information relating to technique and block height during SA for CS, was estimated at 80%. A sample size of 100 patients was calculated with 95% confidence that the true proportion of inadequate documentation would lie between 72.5% and 87.5%.

Data analysis

The data analysis was conducted by the University of Cape Town Statistical Consulting Service by using Strata/IC 16.1 software (Strata Corp. 2019. *Strata Statistical Software: Release 16.* College Station, TX: StrataCorp LLC). Descriptive statistics were used to analyse data. This is presented as mean (standard deviation), or median (interquartile range). Correlation was analysed using the Pearson's chi-squared test and in some instances the Fisher's exact- and 1-sided Fisher's exact test.

Results

The anaesthesia charts were analysed of 100 patients receiving SA for CS. The subarachnoid space was identified in every case. There were 68 emergency and 32 elective operations. Daytime emergency cases (07h30-19h00) were more common compared to after-hour cases (19h00-07h30), at 40 and 28 respectively. Only 1 anaesthesia charts included information on all of the 12 variables required. In 23% and 32% of patients respectively, 7 or 8/12 information points were recorded (Figure 1). Ninety percent of anaesthesia charts had inadequately documentation.

The bupivacaine dose was recorded in 98% (10 mg in 80%), and fentanyl in 97% (10 µg in 91%). The reporting of the use of an aseptic technique was omitted in 5% of cases. The needle type was reported in 78% of patients (atraumatic in all cases), the needle gauge in 85%, and the length in 12%. The vertebral level was reported in 89%. In 66% of patients, the reported vertebral level was L3/4, in 21% L4/5, and in 2% L2/3. The number of attempts was specified in 60% of cases. Failure to document sensory dermatomal block height at the start of surgery is shown in Table 1. In 4 patients the block height was tested on both sides, and in one of these patients a difference in block height was documented.

In 31% of patients, the block height was specified. Failure to document the testing modality occurred in 88 records (Table 2). Loss of sensation to cold, using ethyl chloride spray, was recorded in 6% of patients.

The documentation of block height in the recovery area was recorded in a significantly higher proportion of patients than in the operating theatre – 68% vs 31%, p= <0.001. There was no difference in the proportion of patients with documentation of block height in the recovery area having elective or emergency CS (75.8% vs 71.9%, p=0.45).

Intraoperative supplementary analgesia was reported in 6 women, all post-delivery, and general anaesthesia was required in one patient. Opioids were given post-delivery to all these patients. Two received midazolam and 1 patient ketamine post-

delivery. Supplementation was reported in 9.3% of elective cases and in 5.9% of emergency cases (p= 0.4).

In patients requiring intraoperative supplementation, 5/7 anaesthesia charts indicated the level of sensory block in the recovery area. In 2/5 the reported block height was above the T6 dermatome, and in 3/5 at or below T7 dermatome. The lowest reported dermatomal level was T10, following a CS with a duration of 150 minutes.

Discussion

This retrospective analysis of the documentation by anaesthetists of SA for CS, showed that insufficient information was recorded on the majority of charts. This could impact both upon patient safety and on medico-legal consequences in the event of litigation concerning complications relating to spinal anaesthesia. The major issues are poorly managed pain during surgery, and neurological injury.[2,7,8] A large proportion of anaesthesia providers only reported on 8-9 of 12 variables regarded by the authors as essential information. Most did not report the block height achieved prior to surgery, or the modality of sensory testing. There was no mention of any sensory modality other than cold, and only a small proportion reported any details of motor block.

Pain during operative delivery under SA is the commonest cause of successful litigation in obstetric anaesthesia in the United Kingdom (56/76 [74%] in 21 years).[2] It is therefore of great importance that the anaesthetist records the block level accurately, as well as any associated breakthrough pain and its management. This is both to ascertain that the patient is comfortable, and to ensure there is adequate documentation should litigation ensue. Reliable prediction of surgical anaesthesia may be challenging. It is generally accepted that blockade of cold sensation to a level above the T5 dermatome is required, since this is the spinal cord level at which sensory afferent fibres exit the peritoneal cavity via the greater splanchnic nerve. By convention, three modalities are regularly used to test loss of sensation during SA for CS, namely cold, light touch and pain associated with pinprick. Most general and obstetric anaesthesia textbooks do not specify which sensory modality should be used when performing testing before skin incision.[9] This indicates there is currently no single gold standard. Loss of sensation to light touch *appears* to be the best predictor of adequate surgical anaesthesia, but this has not been agreed upon by obstetric anaesthetists,[1,10,11,18] and assessment of block height using a single modality such as touch may erroneously indicate adequate anaesthesia for CS.[12] Therefore, though controversial, many authors have suggested that more than one modality should be tested during SA for CS. In a UK national survey of the practice of obstetric anaesthetists, the majority of providers tested more than one modality, with cold being the most commonly tested.[13] In general, providers were satisfied if

the sensory block to cold and pinprick was to T4, and touch to T5. Interestingly, the proportion of anaesthesia providers that did not test the block height decreased significantly in the 2010 survey compared to the previous survey done in 2004. This could be a reflection of the medicolegal climate in the UK, and the high incidence of successful litigation for pain during caesarean section.[2,3]

There are many challenges and discrepancies in the testing of block height. For example, the blockade of a testing modality is not 100% at one dermatome and 0% at the adjacent dermatome- a transitional zone exists.[14] There are also differences in interpretation of block height dependent on individual practitioners.[13,18] Additional challenges include the finding that after injection of local anaesthetic in the sub-arachnoid space, sensory blockade of touch, cold and pinprick, develops at different levels. The dermatomal level of sensory blockade to light touch is lower than that of cold and pinprick. Furthermore, the sensory blockade to touch is the last to be established and the first to regress after a single injection of local anaesthetic.[15] The average difference between dermatomal levels blocked for the modalities of cold, pinprick and light touch sensation is only one or two, but because of inter-individual variability, this difference can be up to ten dermatomes.[16-21]

Despite the above difficulties in the exact interpretation of dermatomal block height, it was concerning that this aspect of practice was so poorly documented in this study. The fact that block height was better documented in the recovery area may reflect the incorrect practice of allowing the surgeon to test block height in the operating theatre before commencing the operation. In a descriptive, observational cross-sectional study done in KwaZulu-Natal in 2016, overall only 56% of anaesthesia providers, and only 59% of specialists, reported routine testing of the level of spinal anaesthesia, with considerable variation in the modality tested.[22] This data was however derived from self-reported questionnaires completed by correspondents, and does not reflect actual documentation of adequacy of block as in our study, in which only 31% of anaesthesia providers document sensory block height.

Further literature on the documentation of an adequate spinal block level is sparse. Currently there are no clear published guidelines on the required documentation of spinal block testing before caesarean section. Most hospitals in the UK use specific

anaesthesia charts designed for a particular hospital. Audits on the quality of documentation during regional anaesthesia for caesarean section are listed in Table 3.[23-27]

It is clear that there were many aspects of our audit in which the documentation was poor in comparison with these international audits. This may reflect time constraints in the pressurised environment of a high turnover obstetrics unit. In an audit of obstetric anaesthesia records by Olateju et al,[28] the block height and quality of spinal block were evaluated before and after a lecture on obstetric anaesthesia record - keeping. Block height was poorly recorded both before and after the lecture (0 vs 69%). The documentation of the quality of the block was better recorded after the lecture (52 vs. 99%). No mention was made of the modality used to test the efficacy of SA. Such educational endeavours may be of value in the improvement of overall knowledge and documentation of SA for CS in South Africa. Context-specific guidelines are required providing the minimum standards of practice with respect to documentation during this procedure.

Conclusion

The quality of documentation of procedure and block level during SA for CS was not adequate in this audit of practice in a secondary level dedicated obstetrics hospital in Cape Town, South Africa. National guidelines should be drafted and standardised to improve the quality of these records, in order to improve patient care, and for medicolegal purposes.

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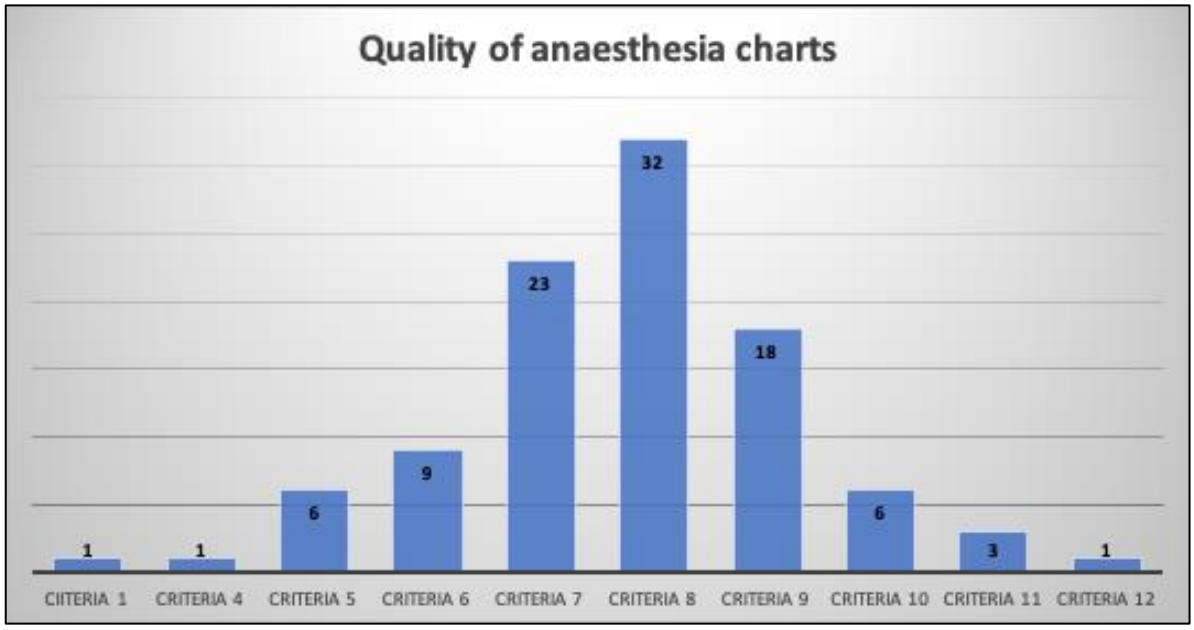
Figure for publication

Figure 1 – Quality of documentation on anaesthesia charts



Tables for publication

Table 1 – Level of experience and documentation of the preoperative sensory block height

Experience	Total cases (%)	Block height not specified	
Registrar	80	54/80 (67.5%)	*p = 0.360
Specialist	20	15/20 (75%)	
All providers	100	69/100 (69%)	

*p value for comparison between registrars and specialists

Table 2 – Level of qualification and documentation of modality used for testing of the sensory block level by registrars and specialists.

Qualification	Total cases (%)	Modality not specified	
Registrar	80	71/80 (88.75%)	*p = 0.45
Specialist	20	17/20 (85%)	
All providers	100	88/100 (88%)	

*p value for comparison between registrars and specialists

Table 3 – Documentation of specific aspects of spinal anaesthesia in published audits

Authors	Sensory dermatome level blocked (%)	Testing modality (%)	Laterality (%)	Intraoperative comfort (%)
Miu M[23]	72	71	57	20
Karuppudayar S[24]	87	58	NR	12
Kurup M[25]	87	54	NR	33
Gorton P[26]	85	NR	NR	63
Uppugonduri S[27]	75	53	45	3

Numbers indicate percentage of charts documenting the individual aspect of the practice of spinal anaesthesia; NR = not recorded.

Chapter 3: Appendices

Appendix 1 – HREC approval letter

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E53-46 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: sumayah.arlefdien@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

09 July 2018

HREC REF: 409/2018

Dr D van Dyk
Division of Anaesthesia & Perioperative Medicine
D-23
NGSH

Dear Dr van Dyk

PROJECT TITLE: EVALUATION OF DOCUMENTATION OF SPINAL ANAESTHESIA PROCEDURE AND BLOCK LEVEL AT CAESAREAN SECTION (MMED Candidate - Dr M du Toit)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30 July 2019.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

We acknowledge that the student: Dr Michiel du Toit will also be involved in this study.

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely

signature removed

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical

Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines.
The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

Appendix 2 – Updated HREC approval letter

UNIVERSITY OF CAPE TOWN

HUMAN RESEARCH ETHICS COMMITTEE
FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee
09 SEP 2020
HEALTH SCIENCES FACULTY

Form FHS006: Protocol Amendment

HREC office use only (FWA00001637; IRB00001938)		
☑ Approved	☑ Type of review: Expedited	☐ Full committee
This serves as notification that all changes and documentation described below are approved.		
Signature Chairperson of the HREC	signature removed Date	9/9/2020

Note: All major amendments must include a local PI Synopsis justifying the changes for the amendment.
Please note that incomplete amendment submissions will not be reviewed.

Comments from the HREC to the Principal Investigator:
Note: The approval of this protocol amendment does not grant annual approval. Please complete the FHS016 / FHS017 form for annual approval at least one month before study expiration.

Principal Investigator to complete the following:

1. Protocol Information

Date (when submitting this form)	08 September 2020
HREC REF Number	406/2018
Protocol title	Evaluation and documentation of spinal anaesthesia procedure and block level at caesarean section
Protocol number (if applicable)	N/A
Principal Investigator	Dr Dominique van Dyk
Department / Office Internal Mail Address	d.vandyk@uct.ac.za (please cc to dominiquevandyk@gmail.com)

1.1 Is this a major or a minor amendment? (see FHS006hlp) Major (tick box) Minor (tick box)	☐ Major	☑ Minor
1.2 Does this protocol receive US Federal funding?	☐ Yes	☑ No
1.3 If the amendment is a major amendment and receives US Federal Funding, does the amendment require full committee approval? Note: Any protocol amendments for Full Committee review MUST be submitted on the monthly HREC submission dates. (Please email an electronic copy to hrec-enquiries@uct.ac.za)	☐ Yes	☐ No

2. List of Proposed Amendments with Revised Version Numbers and Dates

Please itemise on the page below, all amendments with revised version numbers and dates, which need approval.
This page will be detached, signed and returned to the PI as notification of approval. Please add extra pages if necessary.

1) Sample size decreased from 200 to 100: The expected proportion of inadequate documentation of required information relating to technique and block height during SA for CS was estimated at 80%. A sample size of 100 patients was calculated with 95% confidence that the true proportion of inadequate documentation would lie between 72.5 and 87.5%.

2) Clear definition of the primary and secondary outcomes: The primary outcome is the proportion of anaesthesia records demonstrating inadequate documentation of required information, which is defined as <10/12 of the above variables. Secondary outcomes will include a description of the proportion of records omitting each of these factors. In addition, a comparison will be made of the number of required variables documented by registrars and specialist anaesthetists.

3) Capture of data has changed: The anaesthetic charts captured have changed from the first 200 consecutive anaesthetic charts during the month of November 2017 to the first 100 anaesthetic charts each completed by a different anaesthetic provider from 1 January 2018 and proceeding retrospectively till the sample size is achieved.

* The above revisions were made on 25/08/2020

3. Protocol status (tick ✓)

☑	Open to enrolment
☐	No participants have been enrolled
☐	Closed to enrolment (tick ✓)
☐	Research-related activities are ongoing
☐	Research-related activities are complete, long-term follow-up only
☐	Research-related activities are complete, data analysis only

4. Proposed changes will affect: (tick ✓ all the categories that apply)

	Protocol
☐	Study objectives, design (including investigator's brochure, clinical activities, study length)
☐	Study instruments, questionnaires, interview schedules
☑	Sample size
☐	Recruitment methods
☐	Eligibility criteria (inclusion and exclusion criteria)
☐	Drug/device (composition, amount, schedule, route of administration, combination with other drugs/devices, safety information)
☑	Data collection/ analysis

Signature Removed

☐	Principal Investigator. (Please attach revised conflict of interest and PI declaration statements. Refer: sections 7 and 8.4 in the New Protocol Application Form FHS013)
☐	Consent form and information sheet
☐	Recruitment materials (e.g. advertisements)
☐	Administrative (e.g. change in sponsor's name, change in contact information)
☐	Other. Please specify:

4.1 In your opinion, will there be any increase in risk, discomfort or inconvenience to participants?	☐ Yes	☑ No
If yes, please provide a detailed justification/explanation:		

4.2 What follow-up action do you propose for participants who are already enrolled in the study?	
☐	Inform current participants as soon as possible
☐	Re-consent current participants with revised consent/assent forms (append)
☑	No action required
☐	Other. Please describe:

5. Detailed description of the change(s)

Please attach, for each amendment, a summary of all changes which clearly indicates:

i. Old wording (e.g. ~~strikethrough~~ text, CHANGED FROM and CHANGED TO)

ii. New wording (e.g. *italicized*, bold, tracked)

iii. Detailed rationale/ justification/ explanation for each change

6. Ethics Review Levy – cost including vat

Cost for Major Amendments – R5000.00

(Protocols funded by UCT (e.g. departmental funding / student research) and by certain grant funding organizations (e.g. MRC, NRF, CANSA,) are exempt from charges)

For invoicing purposes, please provide:	
Sponsor's name	
Contact person	
Address	

signature removed

Telephone number	
Email Address	

7. Signature

My signature certifies that I will maintain the anonymity and/ or confidentiality of information collected in this research. If at any time I want to share or re-use the information for purposes other than those disclosed in the original approval, I will seek further approval from the HREC.

Signature of PI	Signature Removed	Date	09 September 2020

Appendix 3 – Case Report Form (CRF)

Evaluation of documentation of spinal anaesthesia procedure and block level at caesarean section

Case report form no.: _____ Anaesth ref.:_____

1	Degree of urgency of caesarean section:	Elective		Urgent/emergency	
2	Date and time of anaesthesia:	Date: _____ Time: _____			
		Day Elective		Day Emergency	
		Night Emergency			
3	Level of experience of the anaesthesia provider	Registrar			
		Consultant			
4	Age	< 18 yrs.		> 18yr	
5	**Antisepsis reported**	Yes		No	
6	**Needle used (gauge and length)**	Whitacre		Quincke	
	Gauge specified	Yes		No	
	Length specified	Yes		No	
	Length used:	_____mm			
7	**Lumbar vertebral level**	Yes		No	
		Level used:_____			
8	Number of passes of needle	Yes		No	
9	Number of CSF punctures specified	Yes		No	
10	**Clear CSF flow**	Yes		No	
11	**Paraesthesia on needle insertion documented**	Yes		No	
	If present, distribution specified	Yes		No	
12	**Dose and volume indicated**	Yes		No	
	Bupivacaine dose	_____			
	Fentanyl dose	_____			
13	**Documented modality used for spinal block testing**				
	Modality indicated	Yes		No	
		Cold		Light touch	
		Pinprick		Surgical stimulation	

14	**Block height**	Yes		No	
	Bromage scale documented	Yes		No	
	Differential block height indicated	Yes		No	
	Comparison of left and right sided block	Yes		No	

15	Spinal to skin incision time indicated	Yes		No	
		Time:_____			

16	Skin incision to uterine incision time indicated	Yes		No	
		Time:_____			

17	Spinal to skin closure time indicated	Yes		No	
		Time:_____			

18	**Was intraoperative supplementation required?**	Yes		No	

19.1	Pre-delivery supplementation	GA		N20	
		Opioids		Ketamine	
		Propofol		Midazolam	

19.2	Post-delivery supplementation	GA		N20	
		Opioids		Ketamine	
		Propofol		Midazolam	

20	**Block height documented in recovery**	Yes		No	

21	If spinal supplemented, was the spinal level documented in recovery				
		Yes		No	
		Level:_____			

* Any discrepancies notes/ additional notes

_____
_____
_____
_____
_____
_____
_____

Appendix 4 – Instruction to authors – Southern African Journal of Anaesthesia and Analgesia (SAJAA)

Author Guidelines

Submitted manuscripts that are not in the correct format and without the required supporting documentation specified in these guidelines will be returned to the author(s) for correction and will delay publication.

AUTHORSHIP

Named authors must consent to publication **by signing a covering letter** which should be submitted as a supplementary file. Authorship should be based on substantial contribution to:

(i) conception, design, analysis and interpretation of data;

(ii) drafting or critical revision for important intellectual content; and

(iii) approval of the version to be published. These conditions must all be met (uniform requirements for manuscripts submitted to biomedical journals; refer to **www.icmje.org**); and

(iv) exact contribution of each author must be stated.

DECLARATION OF CONFLICT OF INTEREST

Authors must declare all sources of support for the research and any association with a product or subject that may constitute a conflict of interest. If there is no conflict of interest to declare please include the following statement: The authors declare no conflict of interest.

FUNDING SOURCE

All sources of funding should be declared. Also define the involvement of study sponsors in the study design, collection, analysis and interpretation of data; the writing of the manuscript; the decision to submit the manuscript for publication. If the study sponsors had no such involvement, this should be stated as follows: No funding source to be declared.

RESEARCH ETHICS COMMITTEE APPROVAL

The submitting author must provide written confirmation of Research Ethics Committee approval for all studies including case reports. The ethics committee as well as the approval number should be included.

STATISTICAL ANALYSIS

Authors are advised to involve medical statisticians at the protocol stage of their research project: to plan sample size, and the selection of appropriate statistical tests for analysis and presentation.

PROTECTION OF PATIENT'S RIGHTS TO PRIVACY

Identifying information should not be published in written descriptions, photographs, and pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) gives informed written consent for publication. The patient should be shown the manuscript to be published. Refer to **www.icmje.org**.

ETHNIC CLASSIFICATION

The rationale for analysis based on racio-ethnic-cultural categorisation should be indicated.

CATEGORIES OF SUBMISSIONS

Shorter items are more likely to be accepted for publication, owing to space constraints and reader preferences.

Original articles

Original articles on research relevant to anaesthesia and analgesia should not exceed 3 200 words, no more than 30 references, with up to 6 tables or figures. A structured abstract under the following headings, Background, Methods, Results, and Conclusions is a requirement and should not exceed 300 words.

Clinical Review articles

Review articles relevant to anaesthesia and analgesia should not exceed 2 400 words, with a maximum of 20 references and no more than 6 tables or figures. A summary of 300 words or less is required.

Case reports

Case reports should not exceed 1 800 words with no more than 10 references. Figures are limited to 2 figures and may include images or photographs. The case report should have three headings: Summary (not exceeding 100 words), Case report (with no introduction) and Discussion. Case reports will be published online only. The summary and the URL will appear in the printed version.

Scientific Letters

Scientific Letters should not exceed 2 400 words with a maximum of 10 references. Only one table or illustration is permissible. A structured abstract under the following headings, Background, Methods, Results, and Conclusions, is a requirement and should not exceed 250 words.

Letters to the editor

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Email addresses of all author must be provided.

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