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The prevalence of acute back pain and contributory factors associated with spinal anaesthesia after caesarean delivery at a central hospital

Mutambasere, Abnel Sanders

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The prevalence of acute back pain and contributory factors associated with spinal anaesthesia after caesarean delivery at a central hospital.

Abnel Sanders Mutambasere

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, May 2025

Declaration

I, Abnel Sanders Mutambasere, declare that this research project is my own, unaided work. This research is being submitted for the degree of Master of Medicine at the University of the Witwatersrand, Johannesburg. This work has not been submitted before for any degree or examination at any other university.

Signed 

On the___28TH_____day of_____May_____2025

Dedication

This research project is dedicated my wife, who supported me through this journey. It was all made possible because of you; through the hardships we weathered the storm. To my family and friends, for your continued support and words of encourage, I am eternally grateful. To my late father, Atanas Mutambasere, the dream is alive.

Abstract

Background

Acute back pain is a known complication of spinal anaesthesia for caesarean delivery which often distresses patients. Anaesthetists providing this type of anaesthesia need an in-depth understanding of the prevalence and the factors that contribute to acute back pain in their population.

Objectives

To determine the prevalence, characteristics and factors contributing to acute back pain following spinal anaesthesia for caesarean delivery.

Methods

A total of 80 participants presenting for elective or emergency caesarean delivery were enrolled in the study. An institutional based cross-sectional prospective study was conducted at an academic hospital over a period of two weeks. Participant demographics and factors cited in previous studies as being associated with the occurrence of acute back pain after spinal anaesthesia were recorded. Participants were followed up 48 hours post-operatively in the wards with a questionnaire. Binary logistic regression analysis was done to assess the relationship between contributory factors and acute back pain.

Results

The prevalence of acute back pain after spinal anaesthesia was 25% (*n*=20). Participants described acute back pain as a mild to moderate (median 4.50; IQR 2.00 - 7.00), sharp sensation (45%; *n*=9) localised to the area of injection (55%; *n*=11). There were no statistically significant associations between the contributory factors and the prevalence of acute back pain assessed in this study.

Conclusions

The prevalence of acute back pain after spinal anaesthesia for caesarean delivery was 25% and there were no statistically significant contributing factors.

Acknowledgements

I would like to extend my gratitude to the following people for their contribution to this research project. Dr Elize Dale, Dr Edna Muller and Dr Caryn Lake for the support and guidance during this journey. Dr Dorinka Nel and Dr Jacob Moutlana for their assistance with drafting and evaluating the data collection tool used in this research project. Dr Karel Nzita, for his assistance with data analysis. My heartfelt gratitude goes all the new mothers who participated in this study.

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List of abbreviations

CD	Caesarean Delivery
IASP	International Association for the Study of Pain
CHBAH	Chris Hani Baragwanath Academic Hospital
GA	General Anaesthesia
LOE	Level of experience
BMI	Body Mass Index
ASA	American Society of Anesthesiologists

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Statement

The Research Report consists of a literature review, draft article, study proposal and appendices. The study proposal is included for background references 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 research report to comply with the author guidelines of the South African Journal of Obstetrics and Gynaecology, the journal to which it is intended to be submitted.

1. Literature review

1.1. Background

Spinal anaesthesia is the first type of regional block that was introduced into broad clinical practice and continues to be widely used in surgical patients (1). Most caesarean deliveries are done under spinal anaesthesia barring any contra-indications, therefore providing the best practice of care is crucial. Spinal anaesthesia is the most preferred technique in several other surgical procedures below the umbilicus, lower extremity surgery, anorectal, urological and gynaecological procedure (1).

Research has shown that spinal anaesthesia is an acceptable and safe method in the elderly and in those patients with chronic conditions with unfavourable outcomes with general anaesthesia (2). Several advantages of spinal anaesthesia over general anaesthesia have been cited, namely, a reduction in morbidity and mortality, superior postoperative pain management, avoiding airway instrumentation, early recovery and discharge from hospital and a reduced risk of developing deep vein thrombosis (2).

While spinal anaesthesia is widely accepted as being safer, with serious complications occurring only rarely, it is not without considerable problems. Post lumbar puncture adverse event rates in memory clinics have been shown to be as high as 31% (3). A plethora of studies has been done on a number of post spinal complications; however, a widely underrated and often overlooked complication is the development of acute back pain, which is often linked to patient dissatisfaction and prolonged hospital admission (4).

1.2. Definition of pain

The International Association for the Study of Pain (IASP) defines pain as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage (5). Back pain following spinal anaesthesia has been characterized as being continuous pain around the site of puncture without radicular pain (6).

1.3. Characteristics of back pain following spinal anaesthesia

Numerous pathophysiological theories in the development of back pain after spinal anaesthesia have been postulated. One theory suggests that paraspinal relaxation due to excessive stretching of spinal ligaments and localized tissue damage may result in back pain (7). Back pain

following lumbar puncture was initially termed transient radicular irritation (7). Transient radicular irritation was described as pain originating in the buttocks and radiating to the lower extremities occurring within a few hours after spinal anaesthesia without any neurological findings (7). The term was later changed to transient neurological syndrome (TNS) because of perceived symptomatic overlap with musculoskeletal conditions (7). The pain reported in TNS ranged in intensity from mild to severe lasting up to five days (7). Back pain after spinal anaesthesia is often mild and manifests when the local anaesthesia wears off in about 6 hours, lasting for 72 hours to 1 week (8).

1.4. Implications of back pain following spinal anaesthesia

Despite evidence demonstrating that acute back pain following spinal anaesthesia is temporary and self-limiting, studies have shown that a significant number of patients are reluctant to undergo spinal anaesthesia due to the fear of developing chronic back pain (4). The fear of back pain after neuraxial injection was cited as one of the reasons patients refused to get neuraxial anaesthesia in a study conducted by Rhee et al (9). In this study, 1191 subjects were surveyed following a spinal block and the results revealed a dissatisfaction rate of 4% (n = 54) with 29% of those patients citing backache as the cause of their dissatisfaction (9). The researchers found that the refusal rate to have spinal anaesthesia again was 3.2% (9). While satisfaction rate was 96.3%, side effects still did occur, the most cited side effects were paraesthesia at the site of injection, postoperative nausea and vomiting and postoperative backache (9). It is therefore important that anaesthetists be well informed about the prevalence of acute back pain after spinal anaesthesia in their institutions to provide accurate information to their patients upon request.

Some anaesthetists have struggled deciding on whether they should perform neuraxial blocks in patients with pre-existing back pain for medicolegal reasons or concern of worsening back pain (7). In rarer instances, lower back pain may persist for weeks after the procedure and may become permanent if there was nerve injury involved (10) or it may be a manifestation of serious neurological consequences like epidural abscesses and haematomas (2). A deeper understanding of the prevalence and factors associated with the development of back pain is therefore important.

1.5. Incidence

The reported incidence rate of back pain after neuraxial anaesthesia globally ranges from 2% to 29% (6). However, studies done in developing countries have found significantly higher rates of back pain (1). The prevalence of post spinal backache in a study conducted in Ethiopia was 40.5%, (1) while another study reported that 38.0%, 29.9% and 16.0% of patients had back pain in the 1st, 2nd and 3rd days after spinal anaesthesia (11). These findings were in contrast to the 9-10% incidence reported in a study conducted in Chicago, United States of America (1).

A prospective 1-year follow-up study by Schwabe et al. (10) sampling 122 patients that had undergone spinal anaesthesia for non-obstetric surgery revealed that 10.7% (n = 12) complained of back pain on day 5 post-surgery and 12.3% (n = 15) had pain that persisted after 3 months (10). These findings could not be replicated by Forozeshfard et al. (2) in a prospective 1-year follow-up study done in 2020, involving 410 subjects (2). The researchers in this study concluded that the incidence of low back pain was very low and patients who had received spinal anaesthesia did not experience persistent pain (2). Given the debilitating nature of back pain, it is important that the role of spinal anaesthesia in back pain be appropriately evaluated. Back pain is a global health problem affecting 50% - 80% of people at some point in their lives (1).

1.6. Contributing factors

A study done on the contributory factors for persistent back pain following spinal anaesthesia cited body mass index, history of back pain, spinal needle radius, severity of pain during the lumbar puncture, number of spinal puncture attempts, number of bony contacts and duration of the surgery as relevant risk factors for postoperative back pain (10). Data collected after 4 weeks showed that 5.2% (n = 34) of patients experienced back pain and these were statistically related to body mass index, history of back pain and duration of the surgery (10). The study concluded that back pain after spinal anaesthesia was almost exclusively associated with pre-existing back pain and that patient characteristics and technical factors played less of a significant role (10).

Other factors that have been studied include gender, age, type of surgery, previous spinal anaesthesia and positioning (2). In a randomized control trial by Lee et al. (6) involving 100 patients, the incidence of back pain following a median approach versus a paramedian approach showed a higher incidence of back pain with the median approach 36% (*n* = 18) compared to

the 16% (*n* = 8) with paramedian approach in the early postoperative period (6). Other studies have cited non biomedical factors such as preoperative mood as possible factors in the occurrence of back pain after spinal anaesthesia (8). A prospective observational study revealed a significant association between preoperative depression and the incidence of back pain following spinal anaesthesia (8).

There has also been debate on whether the occurrence of back pain postoperatively might be related to factors other than the type of anaesthesia provided. A study by Brown et al. (12) assessed the incidence of back pain in patients who received general anaesthesia versus those that received spinal anaesthesia (12). The incidence of back pain was 21 % (n = 16) after spinal anaesthesia which was similar to back pain in patients that received general anaesthesia, with an incidence of 19 % (n = 325) (12). The researchers noted that back pain occurred in patients operated in the supine or lithotomy position and that one the of major factors contributing to back pain was the duration of the procedure (12). The authors argued that the development of back pain following spinal anaesthesia was not related to the trauma caused by the puncture needle but rather the stretching of paraspinous ligaments and joint capsules (12).

Several interventions to reduce the incidence of back pain following spinal anaesthesia have been proposed. The use of a 25G radius needle over a 22G radius needle, reducing the number of bony contacts and the addition of dexamethasone have all been shown to reduce the rate of post spinal back pain (4). However, the results pertaining to the spinal needle size seem to be conflicting. In one study, the 22G Quincke needle was shown to cause back pain in a significantly greater amount of patients compared to the 25G Quincke needle at day 1 post operation but no significant differences were noted by the 4th week (4). In contrast, a study by Kim et al. (13) revealed that the choice of needle played no significant influence on the incidence of postoperative back pain (13). The researchers assessed the incidence of back pain at 24, 48 and 72 hours postoperative and noted no significant difference when using a 23G or a 25G Quincke needle (13). A prospective, double-blinded, randomized study was performed to evaluate the effect of local dexamethasone infiltration on the incidence and severity of lumbar pain postoperatively (14). The study showed that the incidence of acute, subacute and chronic back pain was significantly lower in those that had dexamethasone infiltration with lower fentanyl consumption in the first 3 days following gynaecological surgery (14).

1.7. Rationale for this study

Considering the conflicting information on the incidence of back pain in the African population and the varying rates reported, a deep analysis of our own statistics was warranted. The purpose of this study was to determine the prevalence and the factors contributing to acute lower back pain following spinal anaesthesia and to define the severity of the pain in the acute setting. Understanding the risk factors associated with the occurrence of acute back pain after spinal anaesthesia can be used to implement changes in our practice.

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2. Draft article

The prevalence of acute back pain and contributory factors associated with spinal anaesthesia after caesarean delivery at a central hospital.

Authors

Abnel Sanders Mutambasere, Caryn Lake, Elize Dale, Edna Muller

Department of Anaesthesiology, School of Clinical Medicine, Faculty of Health Sciences, University of the Witwatersrand

Abnel Sanders Mutambasere, ORCID iD: 0009-0008-1959-8723
BSc (UCT), BSc. Med (Hons) (UCT), MBBCh (Wits), DA (SA)

Caryn Lake, ORCID iD: 0009-0008-4681-5076
BSc (Wits), MBBCh (Wits), DA (SA), MMed (Anaes) (Wits), FCA (SA)

Elize Dale, ORCID iD: 0000-0002-1014-7431
BA (UP), MBBCh (Wits), DiPEC (SA), DA (SA), MMed (Anaes) (Wits), FCA (SA)

Edna Muller, ORCID iD: 0009-0007-9069-9407
MBChB (UFS), DA (SA), MMed (Anaes) (Wits), FCA (SA)

Corresponding author

Abnel Sanders Mutambasere
Charlotte Maxeke Johannesburg Academic Hospital
Department of Anaesthesiology
7 York Road, Parktown, 2193
Email: abnelsanders@gmail.com

Keywords

Acute back pain, spinal anaesthesia, obstetrics, post caesarean delivery

The prevalence of acute back pain and contributory factors associated with spinal anaesthesia after caesarean delivery at a central hospital.

AS Mutambasere, MBBCh; **C Lake**, MMed (Anaesth); **E Dale**, MMed (Anaesth); **E Muller**, MMed (Anaesth)

[1] *Department of Anaesthesia, Faculty of Health Sciences, University of the Witwatersrand, SA*

***Corresponding author**: A S Mutambasere (abnelsanders@gmail.com)*

Background. Acute back pain is a known complication of spinal anaesthesia for caesarean delivery which often distresses patients. Anaesthetists providing this type of anaesthesia need an in-depth understanding of the prevalence and the factors that contribute to acute back pain in their population.

Objectives. To determine the prevalence, characteristics and factors contributing to acute back pain following spinal anaesthesia for caesarean delivery.

Methods. A total of 80 participants presenting for elective or emergency caesarean delivery were enrolled in the study. An institutional based cross-sectional prospective study was conducted at an academic hospital over a period of two weeks. Participant demographics and factors cited in previous studies as being associated with the occurrence of acute back pain after spinal anaesthesia were recorded. Participants were followed up 48 hours post-operatively in the wards with a questionnaire. Binary logistic regression analysis was done to assess the relationship between contributory factors and acute back pain.

Results. The prevalence of acute back pain after spinal anaesthesia was 25% (*n*=20). Participants described acute back pain as a mild to moderate (median 4.50; IQR 2.00 - 7.00) sharp sensation (45%; *n*=9) localised to the area of injection (55%; *n*=11). There were no statistically significant associations between the contributory factors and the prevalence of acute back pain assessed in this study.

Conclusions. The prevalence of acute back pain after spinal anaesthesia for caesarean delivery was 25% and there were no statistically significant contributing factors.

Spinal anaesthesia was the first type of regional block introduced into broad clinical practice and continues to be widely used in surgical patients today.[1] Spinal anaesthesia is the preferred technique for most caesarean deliveries. This type of anaesthesia is considered safer than

general anaesthesia with complications occurring only rarely.[1] Advantages of spinal anaesthesia are: a reduction in mortality and morbidity, superior postoperative pain management, lower risk of aspiration and early recovery and discharge from hospital.[2] While serious complications are not common, research done in memory clinics on post lumbar puncture adverse events has shown rates as high as 31%.[3] Although information on post spinal complications exists; a widely underrated and often overlooked complication is the development of acute back pain which is often linked to patient dissatisfaction and prolonged hospital admission.[4]

Acute back pain after spinal anaesthesia is often mild, lasting 72 hours to 1 week in about 13 – 30% of patients.[5] Despite the self-limiting nature of the pain documented, studies have shown that a significant number of patients are often reluctant to undergo spinal anaesthesia due to the fear of developing chronic back pain.[4] Some anaesthetists struggle to decide on whether to perform neuraxial blocks on patients with back pain because of medicolegal reasons or concerns of worsening existing back pain.[6]

The reported prevalence rate of acute back pain after neuraxial anaesthesia globally ranges from 2% to 29 %.[7] However, studies done in East Africa have reported prevalence rates as high as 40.5%, compared to the 9 - 10% reported in one study done in Chicago, United States of America.[1] It is therefore important that anaesthetists have comprehensive knowledge regarding the prevalence and the factors associated with the development of acute back pain after spinal anaesthesia in their population. Factors often cited include, body mass index (BMI), history of back pain, spinal needle radius, number of spinal puncture attempts and bony contacts, gender, age and preoperative depression.[2,5,8,9]

In view of the diverse prevalence rates of acute back pain following spinal anaesthesia reported across different regions, a detailed analysis of the South African population was deemed necessary. The objectives of this study were to determine the prevalence of acute back pain after spinal anaesthesia for caesarean delivery at Chris Hani Baragwanath Academic Hospital (CHBAH), to describe the characteristics of the acute back pain and to assess the contributing factors.

Methods

An institutional based cross-sectional prospective study was conducted at CHBAH, a central academic hospital in the south of Johannesburg, South Africa. To determine an appropriate sample size, a review of theatre records was done in the months of August and September of 2022. The average number of patients undergoing caesarean deliveries daily during weekday

working hours (08:00 to 16:00) was found to be 10. The minimum sample size was determined using StatCalc and adjusted for a population size of 100 over a 10-day period. The minimum sample size obtained within a 95% confidence interval was 77, after assuming that the expected prevalence of acute back pain was 29% with a margin of error of 5%. Data was collected from the 31st of July 2023 to the 11th of August 2023. The following were recruited into the study; participants that were > 18 years old, presenting for either elective or emergency caesarean delivery during the hours of 08:00 – 16:00 who received spinal anaesthesia. Participants who were less than 18 years, unable to give informed consent, intubated post operatively and/or had poor neonatal outcomes were excluded from the study.

Data collection

A data collection tool was developed on RedCap®. The quantitative section of the data collection tool was developed to align with the objectives of the study, namely, presence of acute back pain, spinal technique and contributory factors. The qualitative section of the data collection tool was a comprehensive questionnaire developed to describe the characteristics of acute back pain using the verbal pain intensity scale (VPIS) (1 mild pain - 10 severe pain) and an adaptation of the neuropathy pain scale.[10,11] Pain was graded as mild when scored less than 4, moderate when scored 5-6 and severe when the score was greater than 7. A thorough literature review was done, and the questionnaire was evaluated and validated by three senior anaesthetists in the Department of Anaesthesia at the University of the Witwatersrand. Information collected on the data sheet included participant demographics, spinal technique, anaesthetist's level of experience and duration of surgery. Anaesthetists were grouped according to the level of their experience in ascending order from interns (<2 years postgraduate experience), medical officers (non-training post internship doctors) to junior and senior registrars (speciality training doctors <2 years or > 2 years into their training respectively). Spinal technique investigated included the spinal needle size and type, number of attempts and bony contacts. The number of attempts measured was the number of procedures performed starting from the insertion of the introducer and spinal needle through the skin and soft tissues ending with the removal of the stylet[1] and these were grouped into either single or multiple attempts. Data pertaining to the conduct of anaesthesia and surgery was collected by the principal researcher to eliminate bias. The questionnaire was provided to the participants 48 hours post-surgery and explained in a language the patients understood, ensuring clarity where required with the assistance of qualified theatre and ward nursing staff.

Statistical analysis

Data collected was primarily analysed using Statistical Package for Social Sciences (IBM® SPSS®). Descriptive statistics was used to analyse categorical variables using frequencies and percentages and where appropriate, median and interquartile ranges (IQR). Continuous variables such as demographic data were reported using means and standard deviations. Binary logistic regression was used to determine the association between independent variables (continuous and categorical) and the dependent variable (acute back pain after spinal anaesthesia). Adjusted odds ratios, 95% confidence interval (CI), Nagelkerke R^2 and *p*-values were reported to ascertain the strength of the association between the independent variables and the dependent variable. A *p*-value < 0.05 and Nagelkerke $R^2 > 0.2$ were considered statistically significant. GraphPad Prism version 10 was used for chart and graphical representation of data.

Ethical considerations

Ethical approval was granted by the Human Research Ethics Committee of The University of the Witwatersrand (ref. no. MED23-04-160). Permission to conduct the study was obtained from the CEO, the head of the department of Anaesthesia, the head of the department of Obstetrics and Gynaecology at CHBAH and the Department of Health Research of Gauteng (ref. no. GP_202304_014). Written informed consent was obtained from all participants. A unique study number was assigned to each participant to ensure confidentiality.

Results

A total of 89 participants were screened. Nine participants were excluded from the study for the following reasons: poor neonatal outcome (*n*=7), intubation post-surgery (*n*=1) and incomplete consent form (*n*=1). The remaining 80 participants were enrolled into the study. The participants had a mean age of 30.7 (SD 6.8) and a mean BMI of 31.3 (SD 6.9).

The prevalence of acute back pain post caesarean delivery was 25% (*n*=20), with 55% (*n*=11) of these participants indicating that they experienced pain over the injection site. (Fig. 1). The majority of the participants, 70% (*n*=14) indicated that the pain experienced did not radiate. Sites of radiation reported by 30% (*n*=6) of the participants were, lower extremities 33.3% (*n*=2), buttocks 16.7% (*n*=1) and paravertebral regions 50% (*n*=3) (Fig. 1).

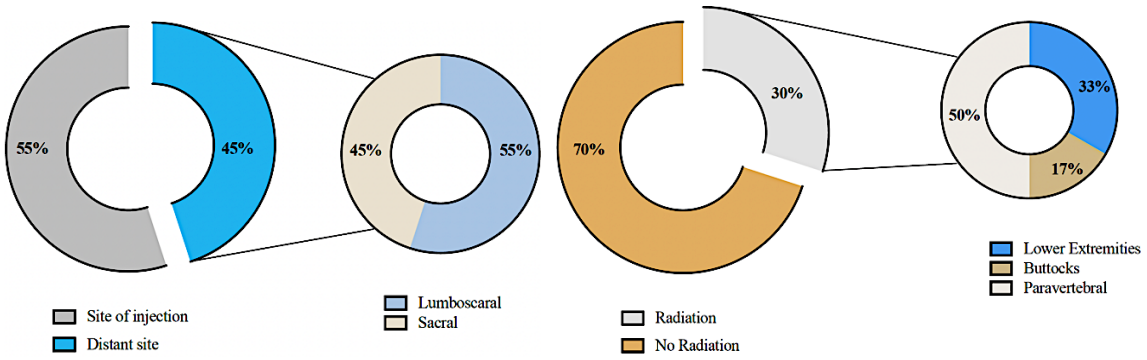

Figure 1. Location of acute back pain.

Participants described the pain experienced as being sharp, 45% (*n*=9), 40% (*n*=8) as dull, 10% (*n*=2) as cold and 5% (*n*=1) as heat (Fig. 2a). Most participants reported experiencing mild to moderate pain, 50% (*n*=10) experienced mild pain (<4), 15% (*n*=3) had moderate pain (5-6) and 35% (*n*=7) experienced severe pain (>7) (median 4.50; IQR 2.00 - 7.00) (Fig. 2b). None of the participants with acute back pain reported having any neurological symptoms.

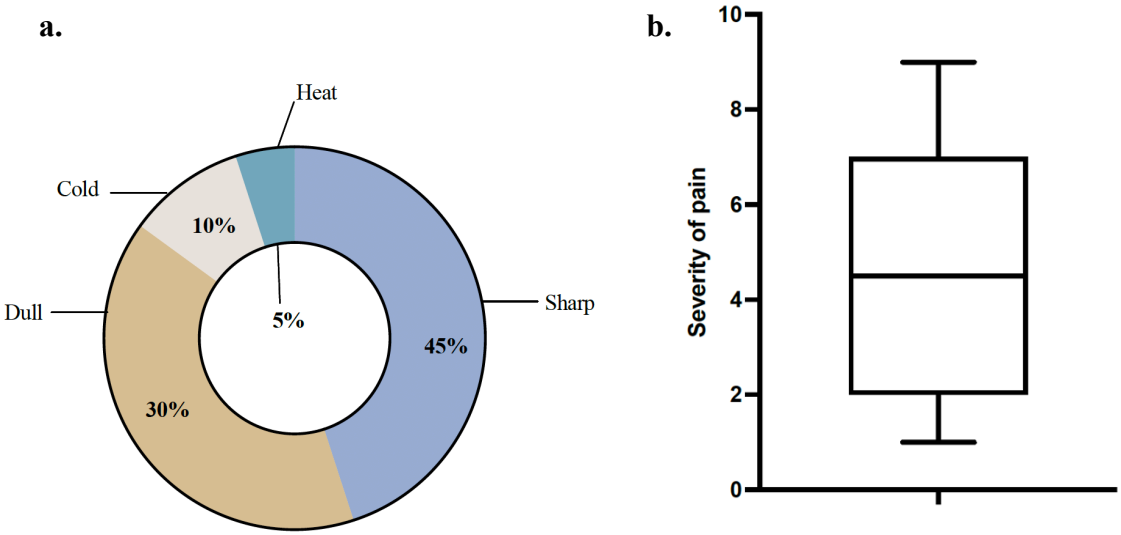

Figure 2. Characteristics of acute pain back. a. The feeling associated with the acute back pain experienced. b. The severity of the acute back pain experienced on the VPIS, represented by the median, interquartile range (IQR), minimum and maximum values.

A comparison of the demographic representation in the group that experienced acute back pain and those that had no acute back pain was performed (Table 1). Statistical analysis of the participant factors showed no significant differences in the two population groups (Table 1). The following participant factors were reviewed, age (adjusted odds ratio (aOR) 0.971; 95%

CI 0.24 - 2.33; *p*=0.308; R^2 0.019), BMI (aOR 1.064; 95% CI 0.33 - 3.47; *p*=0.133; R^2 0.044), American Society of Anaesthesiologists (ASA) status (aOR 1.615; 95% CI 0.52 - 5.06; *p*=0.41; R^2 0.013) and back pain prior to caesarean delivery (aOR 1.588; 95% CI 0.36 - 5.06; *p*=0.543; R^2 0.007) (Table 1).

Table 1. Comparison of participant factors (N=80)

Variable	**Acute back pain (*n*=20), *n* (%)***	**No acute back pain (*n*=60), *n* (%)***	***p* value**
Age (mean), (SD)	30.6 (6.5)	30.7 (6.9)	0.308
BMI (mean), (SD)	29.3 (6.0)	31.9 (7.0)	0.133
ASA status II III	 15 (75) 5 (25)	 39 (65) 21 (35)	0.411
Presence of back pain prior to CD Yes No	 3 (15) 17 (85)	 6 (10) 54 (90)	0.543

BMI = body mass index, SD = standard deviation, ASA = American Society of Anaesthesiologists, CD = Caesarean delivery,

*Percentage unless otherwise indicated

Descriptive and binary logistic regression analyses of the anaesthetic and surgical factors (Table 2) between the two population groups revealed that the level of experience of the anaesthetist was the only statistically significant variable associated with acute back pain based on p value (*p*=0.025) (Table 2). However further analysis of this relationship showed no significant statistical difference (aOR 0.5789; 95% Cl 0.19 - 1.80; R^2 0.189) (Fig. 3) (Table 3). The low R^2 value revealed that this variable accounted for a relatively small proportion of the variance noted in the prevalence of acute back pain (Table 3). Other anaesthetic and surgical factors assessed were, needle size (aOR 0.672; 95% CI 0.07 – 6.40; *p*=0.731; R^2 0.010), needle type (aOR 0.737; 95% CI 0.08 – 7.00; *p*=0.790; R^2 0.001), number of bony contact (aOR 1.116; 95% CI 0.40 – 3.09; *p*=0.237, R^2 0.034) and duration of surgery (aOR 0.732; 95% CI 0.26 – 2.10; *p*=0.562; R^2 0.017) (Table 2) (Table 3) (Fig. 3). While number of attempts did show an

aOR > 1, the p value (>0.05) and R^2 value (<0.2) revealed no statistical significance (aOR 5.24; 95% CI 1.88 – 14.65; *p*= 0.137; R^2 0.121) (Table 2) (Table 3) (Fig.3).

Table 2. Comparison of anaesthetic and surgical factors (N=80)

Variable	**Acute back pain (*n*=20), n (%)**	**No acute back pain (*n*=60), *n* (%)**	***p* value**
Needle size			0.731
22G	1 (5)	4 (6.67)	
25G	16 (80)	43 (71.67)	
26G	3 (15)	13 (21.67)	
Type of needle			0.790
Whitacre	19 (95)	56 (93.33)	
Quincke	1 (5)	4 (6.67)	
Number of attempts			0.137
Single	11 (55)	21 (51.67)	
Multiple	9 (45)	39 (33.33)	
Number of bony contacts			0.237
None	10 (50)	23 (38.33)	
Contact	10 (50)	37 (61.67)	
Anaesthetist LOE			0.025
Junior	15 (70)	33 (30)	
Senior	5 (20)	27 (36.67)	
Duration of surgery			0.562
<1hour	7 (35)	25 (41.67)	
>1hour	13 (65)	35 (58.33)	
G = gauge, LOE = level of experience			

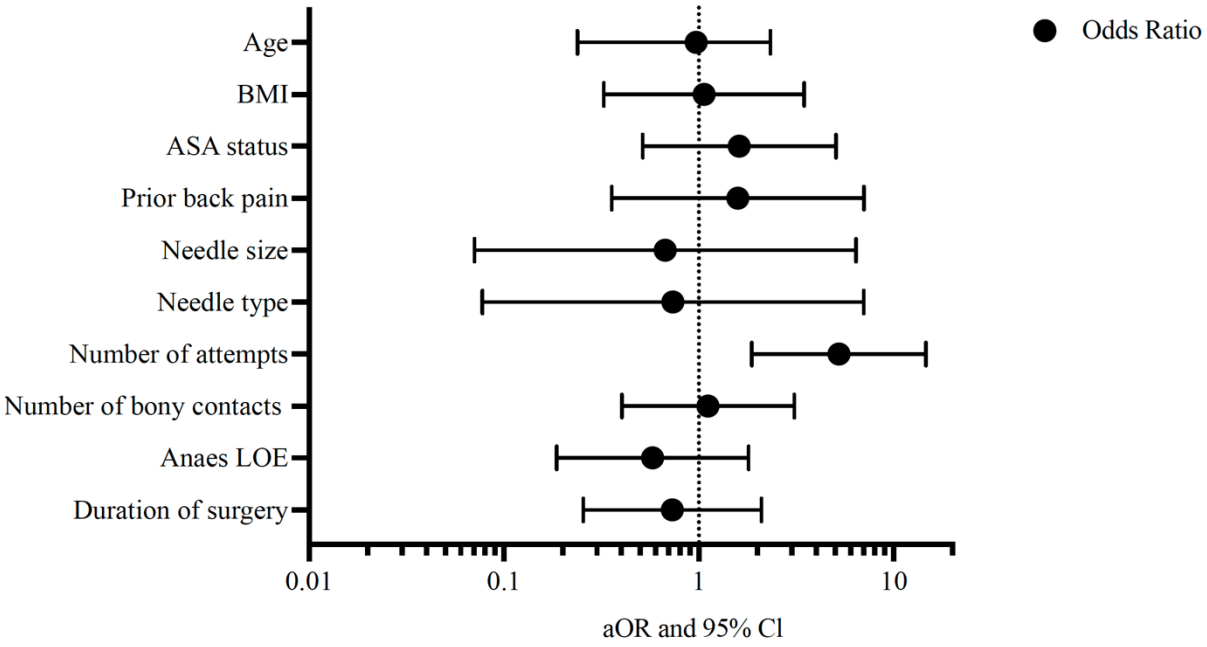

Figure 3: Binary logistic regression analysis of factors associated with acute back pain. BMI = body mass index, ASA = American society of anaesthesiologists, Anaes. LOE = anaesthetist's level of experience, aOR = Adjusted odds ratio, CI = Confidence interval.

Table 3: Model summary of comparison of independent variables (contributory factors) against acute back pain.

	Nagelkerke R^2
Age	0.019
BMI	0.044
ASA status	0.013
Pain prior to surgery	0.007
Needle size	0.010
Type of needle	0.001
Number of attempts	0.121
Number of bony contacts	0.034
Anaes. LOE	0.189
Duration of surgery	0.017

BMI = body mass index, ASA = American society of anaesthesiologists, Anaes. LOE = anaesthetist's level of experience

Discussion

The prevalence of acute back pain in this study at 48 hours post spinal anaesthesia for caesarean delivery was (25%). Studies done in East Africa have reported significantly higher incidence rates of acute back pain when compared to the global average (29%) at 24 hours (38%) and 72 hours (40.5%) post caesarean delivery.[1,12] While the prevalence rate in our study exceeded that reported in the USA (10%),[1] it was relatively comparable to the global average. Suggesting that the standard of perioperative care at CHBAH was on par with rest of the world and that population demographics may have little to no influence on the occurrence of acute back pain after spinal anaesthesia for caesarean delivery.

Acute back pain after spinal anaesthesia has previously been reported as being mild and self-limiting; the treatment of which involves simple analgesics.[2] Schwabe et al.[8] noted that pain following spinal anaesthesia manifests with serious neurological consequences only in rare instances.[8] Most of the participants in our study described acute back pain after spinal anaesthesia as being a mild to moderate sharp sensation limited to the site of injection with no neurological signs. The description provided by the participants in this study was in accordance with the definition of back pain after spinal anaesthesia set in previous studies.[1,7]

Past studies have cited several participant demographic factors associated with the presence of back pain after spinal anaesthesia. Participant factors reviewed in this study were age, BMI, ASA status and the presence of back pain prior to the surgery. There was no statistically significant association between age, BMI and ASA status and the presence of acute back pain in our study. A study by Schwabe et. al,[8] concluded that back pain after spinal anaesthesia was almost exclusively associated with pre-existing back pain and that patient characteristics played less of a significant role.[8] In the current study, there was no association between the presence of back pain prior to the surgery and the occurrence of acute back pain after spinal anaesthesia (p=0.543).

Interventions to reduce the incidence of back pain following spinal anaesthesia have included the use of smaller gauge spinal needles and reducing the number of bony contacts.[4,9] In the present study, 22G Quincke, 25G and 26G Whitacre needles were used and there was no significant association between acute back pain and the size of the spinal needle (p-values>0.05). There was no statistically evident association between acute back pain after spinal anaesthesia and the number of attempts and number of bony contacts in our study.

Researchers have argued that the development of back pain after spinal anaesthesia may not be related to the trauma caused by the needle but rather by the stretching of paraspinous and joint ligaments and other surgical factors.[13] Surgical factors cited were positioning and

duration of surgery.[13] Our study found no statistically supported variation in the occurrence of acute back pain with differing surgical times. All the participants in this study were operated on in the supine position and as such, the relationship between acute back pain and positioning could not be assessed.

Based on the results of our study, acute back pain after spinal anaesthesia was exclusively related to the level of experience of the anaesthetist performing the procedure based on p value alone. However further analysis of this relation revealed this difference accounted for only a relatively small proportion of the variance noted in our study. Our results therefore suggest that level of experience of the anaesthetist in neither statistically nor clinically significant enough h to warrant changes in practice probably due to the small sample size used in the study.

Study limitations

The study was limited to 48 hours post operation. Extending the post operative time may aid in further understanding the evolution of acute back pain following spinal anaesthesia. Data was collected over a two-week period only, lengthening the data collection time may have provided a larger cohort size.

Conclusion

The prevalence of acute back pain following spinal anaesthesia for caesarean delivery was 25% and most participants described acute back pain as being a sharp sensation of mild to moderate intensity limited to the site of injection. An in-depth analysis of the relationship between acute back pain and the contributory factors is required to guide changes in practice and teaching.

Declaration. This research was done in partial fulfilment of the requirements for AM's MMed (Anaes) degree at the University of the Witwatersrand.

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Conflicts of interest. None

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Objectives: what the study intends to find out

Methods: must include study design, number of participants, description of the research tools/instruments, any specific analyses that were done on the data.

Results: first sentence must be brief population and sample description; outline the results according to the methods described. Primary outcomes must be described first, even if they are not the most significant findings of the study.

Conclusion: must be supported by the data, include recommendations for further study/actions.

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3. Study Proposal

The prevalence of acute back pain and contributory factors associated with spinal anaesthesia after caesarean delivery at a central hospital.

Name: Abnel Sanders Mutambasere
Student Number: 540008

Supervisor:	Caryn Lake
	Department of Anaesthesiology
Co-supervisor:	Elize Dale
	Department of Anaesthesiology
Co-supervisor:	Edna Muller
	Department of Anaesthesiology

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3.1. Introduction

Spinal anaesthesia is the first type of regional block that was introduced into broad clinical practice and continues to be widely used today in surgical patients (1). Most caesarean deliveries are done under spinal anaesthesia barring any contra-indications, and as such providing the best practice of care is crucial. Spinal anaesthesia is the most preferred technique in several other surgical procedures below the umbilicus; lower extremity surgery, anorectal, urological and gynaecological procedures based on its perceived reduction in complications (1).

Research has shown that spinal anaesthesia is an acceptable and safe method in the elderly and in those patients with chronic conditions with unfavourable outcomes with general anaesthesia for example, patients with chronic obstructive pulmonary disease, kidney and liver disorders (2). Several advantages of spinal anaesthesia over general anaesthesia have been noted, namely, a reduction in morbidity and mortality, superior postoperative pain management, avoiding airway instrumentation, early recovery and discharge from hospital and a reduced risk of developing deep vein thrombosis (2).

While spinal anaesthesia is widely accepted as being safer, with serious complications occurring only rarely, it is not without considerable problems. Post lumbar puncture adverse event rates in memory clinics have been shown to be as high as 31% (3). A plethora of studies has been done on a number of post spinal complications however; a widely underrated and often overlooked complication is the development of acute back pain which is often linked to patient dissatisfaction and prolonged hospital admission (4). The International Association for the Study of Pain (IASP) defines pain as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage (5). Post spinal back pain has been characterized as being continuous pain around the site of puncture without radicular pain (6).

Numerous pathophysiological theories in the development of back pain after spinal anaesthesia have been postulated. One theory suggests that paraspinal relaxation due to excessive stretching of spinal ligaments and localized tissue damage may result in back pain (7). Back pain following lumbar puncture was initially termed transient radicular irritation (7). Transient radicular irritation was described as pain originating in the buttocks and radiating to the lower

extremities occurring within a few hours after spinal anaesthesia without any neurological findings (7). The term was later changed to transient neurological syndrome (TNS) because of perceived symptomatic overlap with musculoskeletal conditions (7). The pain reported from TNS ranged in intensity from mild to severe lasting up to five days (7).

Back pain after spinal anaesthesia is often mild and manifests when the local anaesthesia wears off in about 6 hours, lasting for 72 hours to 1 week in about 13-30% of patients (8). Despite evidence demonstrating that acute back pain following spinal anaesthesia is temporary and resolves on its own, studies have shown that a significant number of patients may still express concerns and are often reluctant to undergo spinal anaesthesia due to the fear of developing chronic back pain (4). The fear of back pain after neuraxial injection was cited as one of the reasons patients refuse to get neuraxial anaesthesia in a study conducted by Rhee et al (9). In this study, 1191 subjects were surveyed following a spinal block and the results revealed a dissatisfaction rate of 4% (n = 54) with 29% of those patients citing backache as the cause of their dissatisfaction (9). The researchers found that the refusal rate to have spinal anaesthesia again was 3.2% (9). While satisfaction rate was 96.3%, side effects still did occur, the most cited side effects were paraesthesia at the site of injection, postoperative nausea and vomiting and postoperative backache (9). It is therefore important that anaesthetists be well informed about the prevalence of acute back pain after spinal anaesthesia in their institutions to provide accurate information to their patients upon request.

Some anaesthetists have struggled deciding whether they should perform neuraxial blocks in patients with back pain for medicolegal reasons or concern of worsening back pain (7). In rarer instances, lower back pain may persist for weeks after the procedure and may become permanent if there was nerve injury involved (10) or it may be a manifestation of serious neurological consequences like epidural abscesses and haematomas (2). A deeper understanding of the prevalence and factors associated with the development of back pain is therefore important.

The reported incidence rate of back pain after neuraxial anaesthesia globally ranges from 2% to 29%, (6) however studies done in developing countries have found significantly higher incidences of back pain (1). The prevalence of post spinal backache in a study conducted in Ethiopia was 40.5%, (1) while another study reported that 38.0%, 29.9% and 16.0% of patients had back pain in the 1st, 2nd and 3rd days after spinal anaesthesia (11). These findings were in

contrast to the 9-10% incidence reported in a study conducted in Chicago, United States of America (1). These findings seem to suggest differences in the contributing factors, related to the quality of peri-operative care, lifestyle and body habitus of the population surveyed.

A prospective 1-year follow-up study by Schwabe et al. sampling 122 patients that had undergone spinal anaesthesia for non-obstetric surgery revealed that 10.7% (n = 12) complained of back pain on day 5 post-surgery and 12.3% (n = 15) had pain that persisted after 3 months (10). These findings could not be replicated by Forozeshfard et al. in a prospective 1-year follow-up study done in 2020, involving 410 subjects (2). The researchers in this study concluded that the incidence of low back pain was very low and patients who had received spinal anaesthesia did not experience persistent pain (2). Given the debilitating nature of back pain, it is important that the role of spinal anaesthesia in back pain be appropriately evaluated. Back pain is a global health problem affecting 50% - 80% of people at some point in their lives (1) therefore limiting the occurrence of back pain after spinal anaesthesia would significantly alleviate its overall public health burden.

A study done on the contributory factors for persistent back pain following spinal anaesthesia cited body mass index, history of back pain, spinal needle radius, severity of pain during the lumbar puncture, number of spinal puncture attempts, number of bony contacts and duration of the surgery as relevant risk factors for postoperative back pain on day one (10). Data collected after 4 weeks showed that 5.2% (n = 34) of patients experienced back pain and these were statistically related to body mass index, history of back pain and duration of the surgery (10). The study concluded that back pain after spinal anaesthesia was almost exclusively associated with pre-existing back pain and that patient characteristics and technical factors played less of a significant role (10).

Other factors that have been studied include gender, age, type of surgery, previous spinal anaesthesia and positioning (2). In a randomized control trial by Lee et al, involving 100 patients, the incidence of back pain following a median approach versus a paramedian approach showed a higher incidence of back pain with the median approach 36% (n = 18) compared to the 16% (n = 8) with paramedian approach in the early postoperative period (6). Other studies have cited non biomedical factors such as preoperative mood as possible factors in the occurrence of back pain after spinal anaesthesia (8). A prospective observational study revealed

a significant association between preoperative depression and the incidence of back pain following spinal anaesthesia (8).

There has also been debate on whether the occurrence of back pain postoperatively might be related to factors other than the type of anaesthesia provided. A study by Brown et al. assessed the incidence of back pain in patients who received general anaesthesia versus those that received spinal anaesthesia (12). The incidence of back pain was 21 % (n = 16) after spinal anaesthesia which was similar to back pain in patients that received general anaesthesia, with an incidence of 19 % (n = 325) (12). The researchers noted that back pain occurred in patients operated in the supine or lithotomy position and that one the of major factors contributing to back pain was the duration of the procedure (12). The authors argued that the development of back pain following spinal anaesthesia was not related to the trauma caused by the puncture needle but rather the stretching of paraspinous ligaments and joint capsules (12). However, the limited sample size of patients included in the spinal group when compared to the general anaesthesia group brings into question the validity of this study.

Several interventions to reduce the incidence of back pain following spinal anaesthesia have been proposed. The use of a 25G radius needle over a 22G radius needle, reducing the number of bony contacts and the addition of dexamethasone have all been shown to reduce the rate of post spinal back pain (4). However, the results pertaining to the spinal needle size seem to be conflicting. In one study, the 22G Quincke needle was shown to cause back pain in a significantly greater amount of patients compared to the 25G Quincke needle at day 1 post operation but no significant differences were noted by the 4th week (4). In contrast, a study by Kim et al. revealed that the choice of needle played no significant influence on the incidence of postoperative back pain (13). The researchers assessed the incidence of back pain at 24, 48 and 72 hours postoperative and noted no significant difference when using a 23G or a 25G Quincke needle (13). A prospective, double-blinded, randomized study was performed to evaluate the effect of local dexamethasone infiltration on the incidence and severity of lumbar pain postoperatively (14). The study showed that the incidence of acute, subacute and chronic back pain was significantly lower in those that had dexamethasone infiltration with lower fentanyl consumption in the first 3 days following gynaecological surgery (14).

Considering the conflicting information on the incidence of back pain in the African population and the varying degrees reported from one region to another, a deep analysis of our own

statistics is warranted. The purpose of this study is to determine the prevalence and the factors contributing to acute lower back pain following spinal anaesthesia and to define the severity of the pain in the acute setting. The study will further go on to determine whether the prevalence of back pain in our setting is in keeping with the figures reported in the developed world or those reported in other African countries. Understanding the risk factors associated with the occurrence of acute back pain after spinal anaesthesia can be used to implement changes in our practice.

3.2. Problem Statement

Acute lower back pain can be a major deterrent for patients undergoing spinal anaesthesia for caesarean deliveries and has been cited as one of the determining factors in patient satisfaction (4). Therefore, it is important for the anaesthetist administering this type of anaesthesia to have full knowledge of their institution's prevalence rate and the contributing factors to inform patients. The prevalence rate of acute back pain following spinal anaesthesia in caesarean delivery patients at Chris Hani Baragwanath Academic Hospital (CHBAH) will be evaluated in this study.

3.3. Aim

The aim of this study is to determine the prevalence and the factors associated with acute back pain following spinal anaesthesia in caesarean delivery patients at CHBAH.

3.4. Objectives

The primary objectives of this study are to:

- determine the prevalence of acute back pain after spinal anaesthesia for caesarean delivery.
- describe the characteristics and severity of the acute back pain.

The secondary objective of this study is to:

- assess the relationship between acute back pain and the contributing factors.

3.5. Research Assumptions

The following definitions will be used in the study:

Caesarean delivery: Delivery of a foetus through open abdominal (laparotomy) and incision of the uterus (hysterotomy) (15).

Spinal Anaesthesia: Intrathecal injection of small amounts of local anaesthetics at or below the level of L2 (lumbar spine), where the spinal cord terminates, resulting in profound sensory, motor, and sympathetic blockade below the level of the umbilicus (16).

Pain: An unpleasant sensory and emotional experience associated with or resembling that associated with, actual or potential tissue damage, characterised by the following:

- Pain is always a personal experience that is influenced to varying degrees by biological, psychological, and social factors.
- Pain and nociception are different phenomena, pain cannot be inferred solely from activity in sensory neurons.
- Through their life experiences, individuals learn the concept of pain.
- A person's report of an experience as pain should be respected.
- Although pain usually serves an adaptive role, it may have adverse effects on function and social psychological well-being.
- Verbal description is only one of several behaviours to express pain; inability to communicate does not negate the possibility that a human or nonhuman animal experiences pain (17).

Acute lower back pain: Pain that occurs posteriorly in the region between the lower rib margin and the proximal thighs and that is of less than six weeks' duration (18).

Informed consent: The is a process in which a person learns key facts about a clinical trial, including potential risks and benefits before deciding whether to participate in a study. The decision, must be written, dated and signed and appropriately documented, by any person capable of giving consent. Informed consent is a legal procedure taken to ensure the participant is aware of all the risks involved in the study (19). The age of legal consent to clinical treatment in South Africa is 18 years, unless there is good reason to believe that they have mental impairment that compromises their ability to make specific decisions (20). Children 12 years or older mature enough to understand the implications of a proposed treatment may consent on their own behalf (20).

Severity of acute back pain: A verbal pain intensity scale (VPIS) defined as a validated, subjective measure for acute and chronic pain will be used to determine the severity of the pain.

Patients will be asked to choose a number between 0 and 10, where 0 is no pain, 1-3 will represent mild pain, 4-7 moderate pain and scores above 8 will be used to represent severe pain (21).

Contributory factors: The following contributory factors will be investigated in this study; size and type of spinal needle used, number of bony contacts, number of attempts, the duration of surgery, the presence of back pain prior to surgery, level of experience of the anaesthetist and patient demographics (age, body mass index and ASA status). Contributing factors considered in this study were bases on previous studies done (1), (2), (4).

Number of attempts: The number of procedures starting from the insertion of the spinal needle and introducer through the skin and soft tissues ending with the removal of the stylet with anticipation of cerebrospinal fluid flashback (1). This will also encompass needle passes; introducer redirects without complete removal of spinal needle.

Number of bony contacts: The number of contacts with bone structures during an attempt to perform an intrathecal block (1).

Intern: A medical doctor in training who has completed medical school but not licensed to practice independently.

Community service medical officer: A doctor who has completed two years of internship but not yet licensed to practice medicine independently.

Medical officer: A medical doctor who has competed internship and community service but has not entered an advanced training program to become a specialist.

Registrar: A medical doctor undergoing advanced training to become an anaesthetic specialist. Registrars will be considered as senior registrars if they have completed at least 24 months of advanced training and those with less than 24 months of training will be considered as junior registrars.

Adverse neonatal outcome: Defined as neonatal mortality, preterm birth, low birth weight, admission to neonatal intensive care unit and the presence of birth asphyxia with severe sequalae (22).

3.6. Demarcation of study field

The study will be conducted in the CHBAH Maternity post-natal wards. CHBAH is a central academic hospital in the south of Johannesburg and is the third largest hospital in the world, providing services to the population in Soweto and the greater part of Gauteng (23). The hospital has approximately 3200 beds and offers inpatient, outpatient and emergency services (23). Theatre records review showed that the average number of patients that undergo caesarean sections at CHBAH is ten per day during working hours (08:00 to 16:00).

3.7. Ethical considerations

Approval to conduct the study will be obtained from the Human Research Ethics Committee (Medical) (Appendix A) and the Chief Executive Officer at CHBAH (Appendix B). Approval has been obtained from the Graduate Studies Committee of the University of the Witwatersrand and the CHBAH Research Committee (Appendix C), the heads of Obstetrics and Gynaecology (Appendix D) and Anaesthesiology at CHBAH (Appendix E).

Data will be collected on a separate sheet (Appendix F) correlating each patient's hospital number only, to a study number assigned to that patient for the purposes of this study to ensure anonymity. The patient's name and date of birth will not be on the data collection sheet. Patients will be informed of the risks and benefits of participating in the study, the duty of the principal investigator will be outlined. Patients will be asked to sign consent only after they have received all the relevant information regarding the study. The data collected during the interview will be collected on a password protected iPad accessible only to the principal researcher. The data will be collected using a password protected data tool generated using RedCap®. Only the principal researcher will have access and login details to the data collection tool.

The hard copies (if any printed) of the data collected will be kept in a folder in possession of the principal researcher and the digital copies will be kept on password protected external hard drive accessible to the researcher alone. The data will be kept for a maximum of six years there

after all data will be destroyed. When the proposed time has lapsed, all digital data will be erased and all hard copies on the data will be shredded.

Should a patient report experiencing back pain, the doctors involved in the primary care of the patient will be informed. The World Health Organisation (WHO) step ladder for pain management will be used to determine the appropriate analgesia to give to the patient based on the severity of pain reported. The patient will be asked questions to further determine if there are any red flags associated with the back pain (Appendix G). Information will be handed over the primary physicians involved in the care of the patient for further management and appropriate referral.

3.8. Research Methodology

3.8.1. Research Design

An institutional based cross-sectional prospective study will be conducted at CHBAH, over a two-week period.

3.8.2. Study Population

All patients presenting for elective or emergency caesarean delivery at CHBAH, who received spinal anaesthesia, whether successful or not or required conversion to general anaesthesia for other reasons.

3.8.3. Study Sample

Sample Size

The average sample population meeting the study criteria over a two-week period during weekday working hours (08:00 to 16:00) at CHBAH is estimated to be around 100 patients. To determine the minimum sample size StatCalc was used in consultation with a statistician and adjusted for the population size of 100. The minimum sample size obtained within a 95% confidence interval was 77 after assuming that the expected prevalence is 29% with a margin of error of 5%. The reported global prevalence of acute back pain after spinal anaesthesia is 2 – 29%. In this study the calculation of sample size was done using the upper limit of this range (29%).

Sampling method

A randomized sampling technique will be used to recruit participants.

The inclusion criteria for this study are:

- caesarean delivery patients who received spinal anaesthesia
- patients on day 2 (48 hours) post caesarean delivery
- patients not intubated post operatively
- patients older than 18 years.

The exclusion criteria for this study are:

- pre-existing lumbar spine abnormalities
- patients unable to give verbal informed consent
- patients with adverse neonatal outcome.

3.8.4. Data Collection

Data will be collected over a two-week period using a data collection tool that was developed on RedCap® (Appendix F). The quantitative data collection tool was developed to align with the primary and secondary objectives, namely, the presence of acute back pain, severity of back pain, contributory factors and spinal technique. The qualitative section of the questionnaire was developed to describe the characteristics of acute back pain experienced (primary objective 2). Thorough literature review was done to ensure content validity. The data collection tool includes demographic variables such as age, weight, height, body mass index and ASA status. The data collection tool includes a comprehensive questionnaire that will be used to determine presence of acute back pain and its characteristics developed using the verbal pain intensity scale and an adaptation of the neuropathy pain scale. (24), (25) The questionnaire will be completed in a short interview with the principal investigator on day 2 post procedure. The questionnaire was evaluated and validated by three senior anaesthetists in the Department of Anaesthesia at the University of the Witwatersrand.

Information to be collected on the data sheet will also include the size and type of spinal needle used, number of attempts and number of bony contacts. The principal researcher will take academic leave for two weeks to collect data and conduct post operation interviews on day 2 (48 hours after the surgery/day of discharge). The principal researcher will collect all the

required data regarding the administration of the spinal anaesthetic on the day of surgery. The questionnaire will be provided to the patients who meet the sample population criteria. This data will be collected by the researcher each morning over the course of two weeks. During the interview, the patients will be provided with an iPad, where data will be entered. A single iPad to which only the principal researcher will have access to will be used for data collection. The purpose of the study will be explained to the patients, assuring patients that their privacy will be respected and explaining to the patients how data will be collected in a confidential manner.

3.8.5. Data Analysis

The researcher will capture the raw data on RedCap®, the data will be sent to a biostatistician for analysis using Stata^{TM} version 15 (StataCorp, USA). Descriptive statistics will be used to describe categorical variables including characteristics of participants, frequencies and percentages. Bivariate analysis for association between categorical variables will be done using the *Chi-square* (X^2) test and to determine the difference between groups, the independent *t-test* will be used. Each independent variable will be analysed using binary logistic regression to determine the association between these variables and the dependent variable, that is post spinal back pain. Variables with a p value < 0.2 in the bivariate analysis will be included in the multivariate logistic regression to determine the factors associated with acute back pain after spinal anaesthesia for caesarean section. Adjusted odds ratio and a confidence interval of 95% will be reported to ascertain the strength of the association.

3.9. Significance of the Study

Past research has shown that patients' reluctance to undergo spinal anaesthesia is related to previous experience of pain after a spinal injection and that patient satisfaction is also related to the fear of developing back pain post procedure (4), (9). It is a medicolegal and ethical obligation of the anaesthetist performing the procedure to provide the patient with accurate information regarding the incidence or prevalence of acute back pain following spinal anaesthesia in their institution. This study aims to provide information on the prevalence of post spinal back pain at CHBAH, and to identify any modifiable contributing factors. Factors that have been shown to be associated with back pain in studies done in other countries will also be investigated to determine the association between occurrence of post spinal back pain and these factors. Recommendations will be made to alter identified modifiable contributing

factors to decrease the prevalence of post spinal back pain at CHBAH. This study aims to reduce the literature review gap in South Africa and to improve peri-operative practice.

3.10. Validity and Reliability of the Study

The validity and reliability of this study will be ensured by the following measures:

- Clear definition and explanation of what constitutes acute back pain to the patients involved in the study.
- Use of a validated questionnaire.
- Ensuring that patients have questionnaires in a language that they understand.
- To eliminate bias, data will be collected by a single researcher.
- Use of appropriate data collection and analysis tools.
- Use of an appropriate study design.

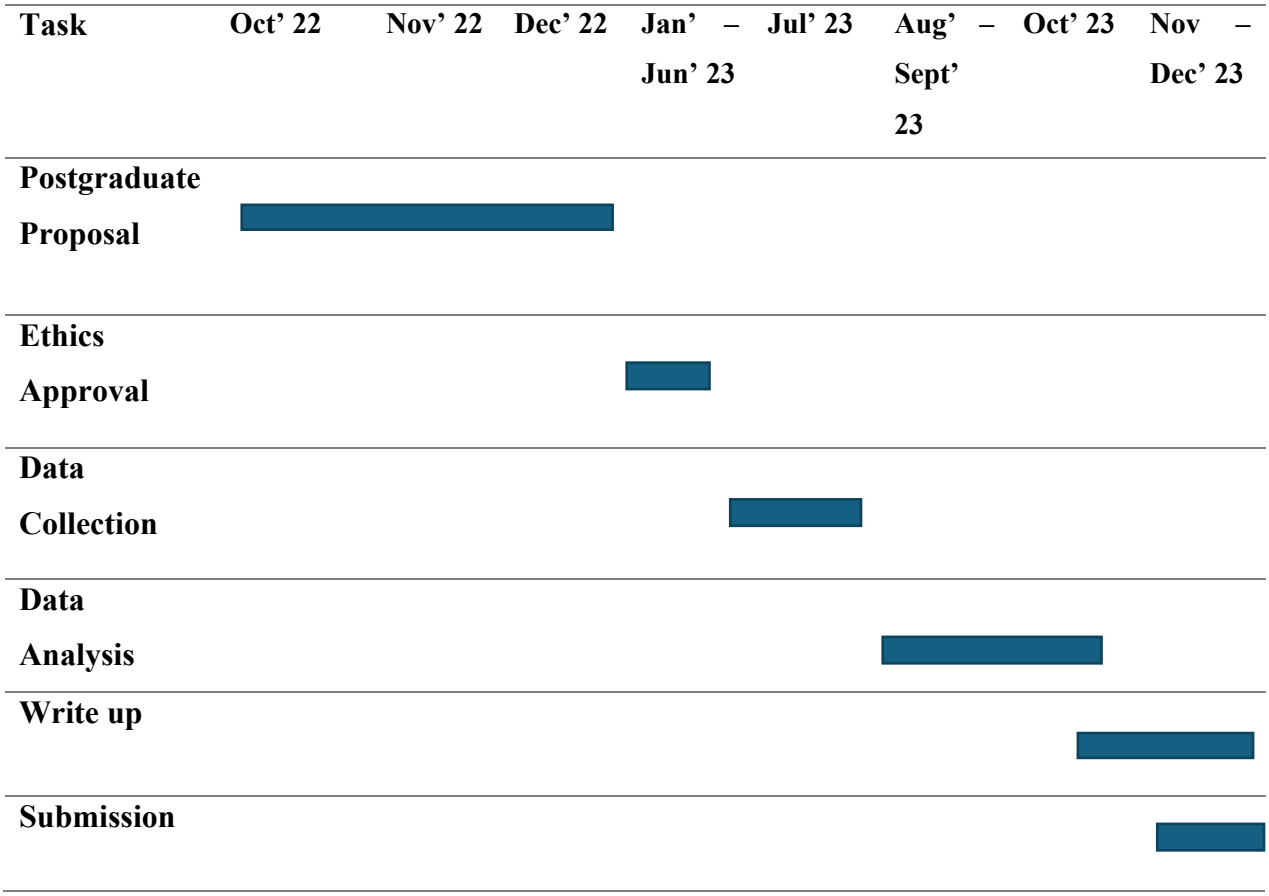
3.11. Potential Limitations of the Study

Differentiating between post spinal back pain from pain experienced in pregnancy may be challenging. Back pain in pregnancy is defined as axial or parasagittal discomfort in the lower back due to biochemical changes which generate stress in the lumbar lordosis and tension in the paraspinal muscles, this may be compounded by compression of great vessels by the gravid uterus decreasing spinal blood flow thus causing lower back pain (26). The definitions will be clearly explained to the patients to provide a concise distinction between the different types of pain in a language they understand.

Inferential statistical analysis will be used, and data collected from this study will be extrapolated to represent an entire population. This data can be an inaccurate representation of the population at large. To minimise the margin of error, statistical analysis has been used to calculate the acceptable, minimum sample size required to accurately reflect the prevalence of post spinal back pain in caesarean section patients.

3.12. Projected Timeline

Time frame:



3.13. Financial Plan:

Description	**Price per item**	**Number required**	**Total**
Printing data sheets	R2.50	300	R750
Printing questionnaires	(R2.50) x 3	300	R2250
Files	R120	2	R240
Printing proposal	(R2.50) x 40	1	R100
Binding proposal	R80	1	R160
Printing final research report	(R2.50) x 80	1	R200
Binding final research report	R80	1	R160
Total cost			**R3180**

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4. Appendices

4.1. Appendix A: Letter from Ethics Committee

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R14/49 Dr Abnel Sanders Mutambasere

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M230538 M230728-B-0005

NAME: (**Principal Investigator**)	Dr Abnel Sanders Mutambasere
DEPARTMENT:	Anaesthesia/School of Medicine Chris Hani Baragwanath Academic Hospital
PROJECT TITLE:	The prevalence of acute back pain and contributory factors associated with spinal anaesthesia after caesarean delivery at a central hospital
DATE CONSIDERED:	26-May-2023
DECISION:	Approved unconditionally
CONDITIONS:	N/A
NOTE:	Application Number: MED23-04-160
SUPERVISOR:	Dr Caryn Lake, Dr Elize Cloete and Dr Edna Muller

APPROVED BY: Dr M Vorster, Co-Chairperson, HREC (Medical)

DATE OF APPROVAL: 27-Jul-2023 **EXPIRY DATE:** 27-Jul-2028

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

DECLARATION OF INVESTIGATOR(S)

I/we fully understand the conditions under which I am/we are authorized to carry out the abovementioned 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** in the month date of convened meeting each year until study is closed. Failure to submit annual report will result in ethics clearance certificate suspension. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. Unreported changes to the application may invalidate the clearance given by the HREC (Medical). Email a signed copy of ethics clearance certificate to HREC-Medical.ResearchOffice@wits.ac.za

Signature of Principal Investigator Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

4.2. Appendix B: Letter from the Chief Executive Officer

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

MEDICAL ADVISORY COMMITTEE

CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

PERMISSION TO CONDUCT RESEARCH

Date: 4th July 2023

TITLE OF PROJECT:

The prevalence of acute back pain and contributory factors associated with spinal anaesthesia after caesarean delivery at a central hospital.

UNIVERSITY: Witwatersrand

Principal Investigator: Dr A S Mutambasere

Department: ANAESTHESIOLOGY

Supervisor : Dr C Lake/Dr E Cloete/ Dr E Muller

NHRD Number: GP_202304_014

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: 04/07/2023

Approved/Not Approved
Hospital Management
Date: 07.07.2023

4.3. Appendix C: Letter from the Post Graduate Committee

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

15 May 2023
Person No: 540008
PAG

Dr AS Mutambasere
3 Castellon
30 Leslie Road
Lonehill
2191
South Africa

Dear Dr Abnel Mutambasere

Master of Medicine in Anaesthesia: Approval of Title

We have pleasure in advising that your proposal entitled *The prevalence of acute back pain and contributory factors associated with spinal anaesthesia after caesarean delivery 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

4.4. Appendix D: Letter from the head of Obstetrics and Gynaecology

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

OBSTETRICS AND GYNAECOLOGY
School of Clinical Medicine

Department of Obstetrics and Gynaecology
Chris Hani Baragwanath Academic Hospital, PO Bertsham 2013, South Africa. Telephone: t 27 11 933 8156 .Fax 2711 938 1534

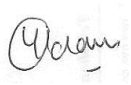
03 April 2023

The Post-Graduate Committee

Re: Dr A. Mutambasere: Permission to conduct study

Permission is hereby granted to Dr A Mutambasere to conduct the study entitled "The prevalence of acute backpain and contributory factors associated with spinal anesthesia after caesarean delivery at a central hospital".
This permission is subject to the candidate obtaining approval from the Wits HREC and the CEO at CHBAH

Yours faithfully,



_____
Professor Y. Adam
Clinical Head and Adjunct Professor
Acting Academic Head
Obstetrics and Gynaecology Department
Chris Hani Baragwanath Academic Hospital
The University of the Witwatersrand

Faculty of Health Sciences
Johannesburg Hospital I Private Bag X39, Johannesburg, South Africa I **T** +27 11 488 3179 I **F** +27 11 643 2522 I www.wits.ac.za

4.5. Appendix E: Letter from the head of Anaesthesia at CHBAH

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL
DIRECTORATE - ANAESTHESIA
Enquiries: Dr P. Mogane
Tel. number: (011) 933-9335
Email: Palisa.Mogane@wits.ac.za

26th January 2023

Department of Anaesthesiology
Chris Hani Baragwanath Academic Hospital
PO Bertsham
2013

To whom it may concern

RE: PERMISSION TO CONDUCT RESEARCH

This serves to confirm that I grant permission for Dr Abnel Sanders Mutambasere (identity number 8708086683182 and persal 92143563) to conduct research at Chris Hani Baragwanath Academic Hospital. The title of the research project is:

"THE PREVALENCE OF ACUTE BACK PAIN AND CONTRIBUTORY FACTORS ASSOCIATED WITH SPINAL ANAESTHESIA AFTER CAESAREAN DELIVERY AT A CENTRAL HOSPITAL"

I would like to wish him luck in this endeavour, and I am happy to support him wherever possible.

Yours sincerely.

Dr Palesa Mogane
Chief Specialist and head of Department
Department of Anaesthesiology
Chris Hani Baragwanath Academic Hospital
University of Witwatersrand
Email: Palesa. Mogane@wits.ac.za

4.6. Appendix F: Data Collection Sheet

Study Information Sheet

The prevalence of acute back pain and contributory factors associated with spinal anaesthesia after caesarean delivery at a central hospital.

Good day,

Congratulations on the birth of your baby. My name is Abnel S. Mutambasere, I am a Master of Medicine (Anaesthesia) candidate. I am currently doing research on the prevalence of post spinal back pain in caesarean delivery. The purpose of this research study is to determine how often patients experience pain after receiving spinal anaesthesia for caesarean delivery and the factors that may be contributing to this back pain.

I am inviting you to take part in this research study. Participation in this study is purely voluntary, you are allowed to refuse or to withdraw your response at anytime within 2 months after taking part in this study. I will provide information on how to contact me at the end of this survey. The information collected within this research study will be used for academic purposes and only shared with the Departments of Anaesthesia and Obstetrics and Gynaecology. The findings may be published in a scientific journal article. The data collected in this study will be used as an auditing mechanism to evaluate the performance of the department and will be utilised to propose changes in practice, if deemed necessary.

I will be collecting information on how the spinal anaesthesia was given to you, as well as demographic information such as your age, weight and height which I will take from your hospital file. I ask your permission to collect this information from your file. I will then follow up with you in the ward 2 days after the operation to ask you questions on how you are feeling. The survey will not take more than 5 minutes and I will be available to clarify any issues. Thank you for your contribution.

Your identity will not be shared with anyone. The only person who will have access to your identity will be myself and I will assign a study number to you. You will only be referred to by the study number in this study. There will be no consequences for the responses provided.

Please feel at ease to provide information as truthfully as possible. If at any point, there is something you are unsure of please inform me. If I fail to satisfactorily resolve the matter you can escalate your concerns to one of the supervisors or the chairperson of the Human Research Ethics Committee, details will also be provided.

This study has been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand, Johannesburg. A principal function of this Committee is to safeguard the rights and dignity of all human subjects who agree to participate in a research project and the integrity of the research.

Consent Form





I can confirm that I, _____, agree to participate in his study on the prevalence of acute back pain and the contributory factors associated with spinal blocks in caesarean section patients. I can confirm that the purpose of this study has been explained to me by the principal researchers and that I have not been coerced into participating.

Signature: _____ Date: ____/_____/_____

I, Abnel Sanders Mutambasere, the principal researcher can confirm that I have adequately explained the benefits and risks of participating in this study to the patient. I can confirm that all the data collected will remain confidential and the identity of the participant will not be compromised.

Signature: _____ Date: ____/_____/_____

Data collection tool

Please complete the survey below.

Thank you!

Patient Demographics	
Age (in years)	_____
Weight (Kgs)	_____
Height (metres)	_____
BMI	_____
ASA Status	◯ ASA 1 ◯ ASA 2 ◯ ASA 3 ◯ ASA 4 ◯ ASA 5
Prevalence	
Are experiencing any back pain that was not present before the operation?	◯ Yes ◯ No
Characteristics	
Where are on your back are you experiencing pain?	◯ In the area of the injection site ◯ In an area distant to the injection site
Please show the interviewer the area where the pain is located. (Choose all that applies)	☐ Sacral ☐ Lumbosacral ☐ Thoracolumbar ☐ Thoracic ☐ Other
Describe other location	_____
Does the pain radiate?	◯ Yes ◯ No
If yes, where does it radiate	◯ Buttocks ◯ Lower extremities ◯ Upper back ◯ Other
Specify other radiation	_____

What does the pain feel like?	◯ Heat ("burning" "on fire") ◯ Dull ("aching", "like a bruise") ◯ ("like a knife", "like a spike", "jabbing", "like jolts") ◯ Cold ("like ice", "freezing") ◯ Other
Specify other character	_____

Severity of the back pain

How severe is the pain?	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10
Did you have back pain before the procedure?	◯ Yes ◯ No
Is the pain different? If so, please provide a brief description.	_____

Spinal technique

What was the size of the spinal needle?	◯ 20G ◯ 22G ◯ 25G ◯ 26G ◯ 27G
Which type of spinal needle was used?	◯ Quincke ◯ Whitacre ◯ Sprotte ◯ Gertie Marx ◯ Pencan
Number of attempts	◯ One ◯ Two ◯ Three ◯ Four ◯ Five ◯ Six ◯ > Seven
Number of bony contacts	_____
Converted to GA	◯ Yes ◯ No

Anaesthetist Demographics

Level of experience	◯ Intern ◯ Community Service Medical Officer ◯ Medical Officer ◯ Junior Registrar ◯ Senior Registrar ◯ Consultant

Surgical Factors	
Duration of surgery	◯ < 1hour ◯ > 1 hour < 2 hours ◯ > 2 hours

Contact details:

Principal researcher: Dr Abnel S. Mutambasere

Cell: 0828909981

Email: abnel.mutambasere@wits.ac.za

Supervisors: Dr Caryn Lake

Cell: 0845544891

Email: caryn.lake@gmail.com

Dr Elize Dale

Email: lizziecloete@gmail.com

Dr Edna Muller

Email: dr.evdm@gnmail.com

Wits Human Research Ethics Committee (Medical) Chairperson

Tel: 011 717 1252 / 2700 / 1234 / 2656

Email: hrec-medical.reserachoffice@wits.ac.za

Please feel free to contact me if you have any questions.

Thank you.

4.7. Appendix G: Back pain red flags questionnaire

Red Flags

History of recent trauma?	◯ Yes ◯ No
Have you been experiencing any unexplained weight loss?	◯ Yes ◯ No
Do you have any neurological symptoms (numbness, tingling, burning)?	◯ Yes ◯ No
Age > 50	◯ Yes ◯ No
History of fever?	◯ Yes ◯ No
History of intravenous drug use?	◯ Yes ◯ No
History of steroid use?	◯ Yes ◯ No
History of malignancy?	◯ Yes ◯ No
Score on history	☐ < 1 ☐ >1 < 3 ☐ > 3
Further management recommended:	_____

4.8. Appendix H: Validation of questionnaire

The prevalence of acute back pain and contributory factors associated with spinal anaesthesia after caesarean delivery at a central hospital.

Face validity:

Questions to consider for face validity:

- Are the components of the measure (e.g., questions) relevant to what's being measured (the objective)?
- Does the measurement method seem useful for measuring the variable?
- Is the measure seemingly appropriate for capturing the variable?

Scale:

1. The test is completely appropriate for measuring a certain construct.
    - No need to change anything
2. The test is mostly appropriate.
    - Minor adjustments
3. The test is somewhat appropriate.
    - Is a good question, but doesn't specifically answer the objective and needs clarification or modification
4. The test is neither appropriate nor inappropriate.
    - Consider whether the question adds benefit to the study
5. The test is somewhat inappropriate
    - The question doesn't answer the question but may become valid after minor modifications or clarification
6. The test is completely inappropriate for measuring a certain construct
    - Remove the question completely

Question	Scale	Comment
Demographics • Age • Weight • Height	2	The options for ASA are not appropriate. An ASA 6 patient will definitely not consent to the study and thus meets an

• BMI • ASA • Level of experience		exclusion criteria! (and neither will the family, or the recipients of her organs give consent) An ASA 5 patient will also likely meet the exclusion criteria, but keep ASA 5 in your options I will have a section for patient demographics and a separate section for anaesthetist demographics) Also, has any of the studies looked at patients' parity and whether they have previous spinal anaesthesia? I think those may be valid questions
Objective 1: Question: Determine the prevalence of acute back pain after spinal anaesthesia for caesarean section Question: Do you have acute back pain?	2	Your definition of acute back pain is referenced to an Ethiopian study where it is the definition of POST-SPINAL BACK PAIN not acute back pain. Definition from Kinkade in *American Family Physician 2007:* Acute low back pain is defined as pain that occurs posteriorly in the region between the lower rib margin and the proximal thighs and that is of less than six weeks' duration Your objective doesn't state that you are determining the prevalence of post-spinal back pain; but that you are looking at acute back pain after spinal anaesthesia. It is not the same. The strict definition that you gave (which

		is for post-spinal pain) is a very specific definition that limits it to the area where the injection was done, and without radiation. The benefit of looking at acute back pain post spinal, is that you can also look for pain in areas other than the injection site and pain that are not just tingling or tenderness. Should you maybe keep your objective as acute back pain (with it's correct definition) and determine the number of patients with acute back pain that also fit the definition of acute post-spinal pain.
Objective 2: Describe the characteristics of the acute back pain		
Question 1: Where exactly is the pain? Answer: • At the injection site • A level below injection site • A level above the injection site • Other	3	**Is the question relevant to what is being asked?** The question is relevant to determine the characteristics. However, the answer is not relevant as it only describes part of the construct. (unless you want to keep it strictly as post-spinal back pain) The word *exactly* is a very narrow concept. Some forms of pain are well localized while the distribution of others is more widespread, vague, with poorly defined borders. There may also be multiple areas of pain. With these answers you are biased towards expecting the pain to be in the vicinity of the injection site because

		your study is looking at pain after spinal.
		It may also be difficult to clearly determine if the pain is exactly where the needle went in, or a level above or below. What if there were multiple attempts at more than one level?
		
		Suggestion: (choose all the applies)
		• In the area of the injection site
		• In an area distant to injection site
		  ○ Sacral
		  ○ Lumbosacral
		  ○ Thoracolumbar
		  ○ Thoracic
		Does the measurement method seem useful for measuring the variable?
		Are you going to examine the patient to determine where the pain is, or does she need to answer the questionnaire (not very clear from your methodology)
		If you are going to examine her and choose the correct answer, then the measurement method is useful for measuring the variable.

Question 2: Does the pain radiate?	1	Both question and answer are appropriate for answering the objective
Question 3: What does the pain feel like?	1	Both question and answer are appropriate for answering the objective

Question 4: How severe is the pain? Answer: Scale without numerical value	2	The question is mostly appropriate in measuring the construct. The answer may be a bit problematic statistically as it doesn't have numerical values. Are you going to ask the patient to put a point on the slider directly on the Redcap form (is it going to be on your cellphone or laptop) or is the form going to be paper based and then you enter the data afterwards? The value of having numerical values is that there isn't uncertainty about whether the value is seven (for instance) or 7.8 (which is rounded to 8). It is however not a major issue and would be perfectly fine to keep it as is
Secondary Objective: Assess for contributors to back pain post spinal		
Question: Did you have back pain before the procedure? (I assume this is one of the questions looking for contributing factors)	1	Simple question; simple answer The question is appropriate to answer the objective
Question: Is the pain different? Discuss	1	Question is valid as it answers the objective
Objective 3: Factors associated with acute back pain (based on the assumption that you want to look at the technical aspect of the spinal)	?	It is difficult to say whether the question is appropriate and valid as I don't know which objective it is supposed to answer The options seem to make sense, but validity depends on answering the questions above

Validation of questionnaire changes

Changes Suggested	**Changes done**
Objective 1	
Question: Do you have acute back pain? (Rephrase the question to be clear to the patient)	Question changed to: Are you experiencing any back pain that was not present before the operation? Resolutions: The definition of acute back pain changed from that of post-spinal back pain to that of acute back pain.
Objective 2:	

Question 2: Where exactly is the pain?	Question changed to:
	Where are on your back are you experiencing pain?
	
	Answers:
	Choose all the options that apply to your pain
	• In the area of the injection site
	• In an area distant to the injection site
	  o Sacral
	  o Lumbosacral
	  o Thoracolumbar
	  o Thoracic
	The patient will be required to answer the questionnaire.

Question 4: How severe is the pain? Answer: Scale without numerical value	Resolution: Scale changed to numeric scale. The data form will be completed on an iPad which will be provided to the patient.

The question is mostly appropriate in measuring the construct. The answer may be a bit problematic statistically as it doesn't have numerical values. Are you going to ask the patient to put a point on the slider directly on the Redcap form (is it going to be on your cellphone or laptop) or is the form going to be paper based and then you enter the data afterwards? The value of having numerical values is that there isn't uncertainty about whether the value is seven (for instance) or 7.8 (which is rounded to 8). It is however not a major issue and would be perfectly fine to keep it as is	
Objectives updated: What exactly is the difference between your 3rd objective under primary objectives, and your secondary objective? The one looks to describe factors associated with back pain; and the other looks to assess factors contributing to back pain. What exactly is the difference between describe and assess in this regard? Which questions pertain to the description of the factors, and which questions pertain to the assessment of the factors?	Resolution: The primary objectives of this study are to: • determine the prevalence of acute back pain after spinal anaesthesia for caesarean section • describe the characteristics and severity of the acute back pain The secondary objective of this study is to: • assess the acute back pain and contributing factors.

4.9. Appendix I: Approval letter of validation and proposal changes by Post Grad Committee



GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

GAUTENG DEPARTMENT OF HEALTH
DR B GARDNER
HOD DEPT OF ANAESTHESIA
HELEN JOSEPH HOSPITAL
PRIVATE BAG X47
AUCKLAND PARK
2006
011 489 0108/082 575 1736
Brian.Gardner@wits.ac.za
02/05/2023

Postgraduate Office
Faculty of Health Sciences University of the Witwatersrand

Dr A Mutambasere M Med proposal: **The prevalence of acute back pain and contributory factors associated with spinal anaesthesia after caesarean delivery at a central hospital**

Dear Kgomotso Tlala,

Dr Abnel Mutambasere, student number: 540008 has made the suggested corrections to his proposal to my satisfaction.

Yours sincerely,



Dr Brian Gardner

Chair Postgraduate Committee October 2022

4.10. Appendix J: Turnitin report



Final Research Report-1.docx

ORIGINALITY REPORT

13%	7%	9%	2%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	Tekgül, Zeki T., Sinan Pektaş, Murat Turan, Yücel Karaman, Meltem Çakmak, and Mustafa Gönüllü. "Acute Back Pain Following Surgery under Spinal Anesthesia", Pain Practice, 2014. Publication	2%
2	www.ncbi.nlm.nih.gov Internet Source	2%
3	Jung Ha Lee, Dae Hun Yoon, Bong Ha Heo. "Incidence of newly developed postoperative low back pain with median versus paramedian approach for spinal anesthesia", Korean Journal of Anesthesiology, 2020 Publication	1%
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