UNIVERSITY of RWANDA

COLLEGE OF MEDICINE & HEALTH SCIENCES
SCHOOL OF MEDICINE& PHARMACY

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Incidence, risk factors and severity of post dural puncture headache in patients who underwent caesarean section in three hospitals in RWANDA.

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DECLARATION

I, Clémentine UWIHOREYE, declare that this dissertation is the result of my own work and has not been submitted to any other university for similar or any other degree award.

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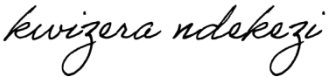
Dr. Jackson NDEKEZI KWIZERA 

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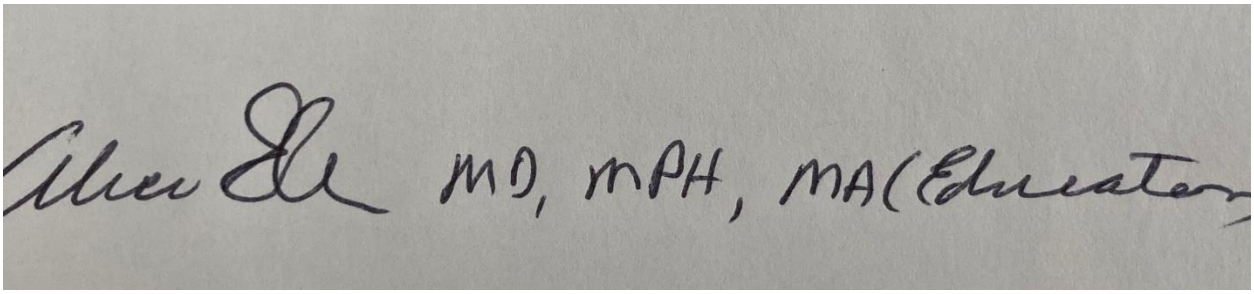

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DEDICATION

I would like lovingly to dedicate this thesis to my husband and children for having understood the reason for leaving them for years to embark on a journey normally perceived as for single persons. This master's qualification is in recognition of your support and may continuously remind you to move confidently in the direction of your dreams.

ACKNOWLEDGEMENT

There are as many people as institutions without whom this thesis would not have been produced and to whom I am greatly thankful. I would like to thank the Government of Rwanda for its commitment to invest in its people through education and therefore for having provided full scholarship to pursue my studies as well as the University of Rwanda, College of Medicine and Health Science (UR-CMHS) in collaboration with the Ministry of Health and Higher Education Council for all my postgraduate studies. It has been a privilege to have Ass. Prof. ALICE EDLER and Dr.Françoise NIZEYIMANA as the main supervisors to whom I would like to express my deepest gratitude for their continued encouragement, constructive feedback, expertise, and academic support that they provided at every stage of the research process. My sincere thanks and appreciation go also to Dr. Claudine Uzamukunda and Dr. Jackson Kwizera Ndekezifor their advice during the research process.

I consider myself fortunate to have the support, patience, and love of my family especially my husband who had to take care of children in my absence, my children for understanding why mammy had to leave them for these last four years. My deepest gratitude is extended to my dear friends, comrades, you also deserve a word of thank you.

Wishing you all the Heavenly blessings.

ABTRACT

Background: PDPH is common in obstetric patients who have undergone spinal anesthesia or epidural anesthesia with an accidental dural puncture. Spinal anesthesia is an inexpensive, safe, rapidly used regional anesthesia technique which can be conducted by anesthesiologists, non-physician anesthetists and nurse anesthetists for Cesarean section but associated with different complications which include post dural puncture headache. The aim of this study was to identify incidence, risk factors and severity of post dural puncture headache in parturient who underwent elective or emergency Cesarean section under spinal anesthesia in three hospitals in Rwanda.

Methods and material: This is a prospective study in three selected hospitals located in Kigali City, Rwanda. Data collected were demographic characteristics, previous surgical history regarding to C-section, presence of PDPH on previous C-section or on current and its characteristics. There after descriptive statistics and inferential statistics were used to display the frequency and to identify risk factors of PDPH. Each independent variable and the dependent variable was analyzed by using binary regression and was considered as significant if their P value is <0.2 and was used in multivariate logistic regression to mitigate the co-founding. On multivariate logistic regression model, the significant risk factors are those with a P value less than 0.05.

Results: Thirty three percent of 261 parturient developed PDPH. The severity of PDPH was moderate at 44.8%, mild at 39.1% and the small portion of16.1% was severe. Body Mass Index (BMI) < 25 $kg.m^{-2}$, PDPH after previous cesarean section were statistically significantly associated with the occurrence of PDPH with the following values 0.000, and 0.036 respectively

Conclusion: A high incidence (33.3 %) of post dural puncture headache was found among 261 parturient who were recruited in this study. The severity of this PDPH was usually ranging from mild, moderate, and rarely severe**.** Significant risk factors were body mass index<25 $kg.m^{-2}$, prior PDPH after previous C/section.

Key words: Epidural anesthesia, post dural puncture, spinal anesthesia, spinal needle.

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LIST OF ABREVIATIONS

1. BMI: Body Mass Index
2. CHUK: Centre Hospitalière Univeristaire de Kigali
3. CMHS: College of Medicine and Health Science
4. CS: Cesarean Section
5. CSF: Cerebral Spinal Fluid
6. DH: District Hospital
7. G25: Gauge 25
8. IRB: Institutional Review Board
9. IVF: Intravenous Fluid
10. MD: Medical Doctor
11. MRI: Magnetic Resonance Imaging
12. PDPH: Post Dural Puncture Headache
13. UR: University of Rwanda
14. USA: United State of America

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CHAPTER I: INTRODUCTION

This study is about incidence, risk factors, and severity of post-dural puncture headache in patients who underwent cesarean section in three hospitals in Rwanda, the introduction includes the background, problem statement, the aim of the study, objectives, research questions, and the operational definitions.

1.1 Background

Spinal anesthesia also named spinal block or subarachnoid block; is a form of regional anesthesia achieved by injecting a local anesthetic into subarachnoid space by fine needle. The first operation with this form of anesthesia was performed in 1898 in Germany by August Bier. (1) It is an inexpensive, safe, rapidly administered regional anesthesia. Spinal anesthesia can be administered by anesthesiologists, non-physicians' anesthetists and nurse anesthetists for cesarean section. Spinal anesthesia is associated with complications which include post-dural puncture headache (PDPH). (2)

PDPH was first defined in 1899 by August Bier. (1) The headache was described as painful pressure in the head, aggravated by upright position and relieved by lying horizontally. (1) PDPH occurs after deliberate puncture of the dural and arachnoid matters for spinal anesthesia, or incidental dural puncture during epidural procedures. (3) PDPH is common in obstetric patients who have undergone spinal anesthesia or epidural anesthesia with an accidental dural puncture.(2) The pathophysiological mechanisms are associated with cerebral spinal fluid (CSF) leakage through the puncture site by needle. This loss of CSF produces a compensatory mechanism of blood vessel dilation to maintain constant intracranial pressure. This vascular dilation results into PDPH. (3), (4), (5)

The review of articles by authors from Iran showed the overall incidence of PDPH after dural puncture ranging from 0.1% to 36%. (6) However, a meta-analysis of obstetrics studies done in Canadian and USA universities showed an incidence up to 52.5%. (7) An observational, prospective study conducted in Spain at Hospital La Paz; Madrid showed a higher incidence of 59% for PDPH. (8) A study conducted in USA by Monserrate et al found different onset times for

PDPH. Immediate PDPH was defined as before 24 hours postoperatively was found to have an incidence of 21.6% while incidence of delayed PDPH (occurring greater than 24) was 17.5%. (9)

A study conducted in Jordan identified risk factors which include repeated attempt punctures and the history of tension headache. (10) A similar study conducted at Sylvanus Olympio University Hospital of Lomé in Togo also found a relative incidence of PDPH of 6.5% and risk factors of young adult, obstetric surgery, low and normal BMI. (10) The study performed at Aga Khan University Hospital; Nairobi determined an incidence of PDPH after cesarean section of 20.35%. (2) A study done in India to determine incidence of PDPH and to assess its management found the incidence 3.9%. (11)

Both the gauge and the type of the needle have been shown to have differing rates of PDPH. The use of the large needles was found to significantly increase the development of PDPH when compared to the use of small gauge needles. (14) The study conducted in United Kingdom at King's College Hospital to compare the Quincke needle with the Sprotte needle found the incidence of 24.4% with Quincke needles and 12.2% with Sprotte needles. (7) A Meta – analysis study conducted by Chinese authors found the rate of 4.3% of PDPH in the participants who underwent spinal anesthesia with Whitacre spinal needles and 6.4% with Quincke spinal needles. This study also found that the use of Whitacre spinal needles to be associated with a low incidence of PDPH. (12) Rates of PDPH correlate positively with the size of the spinal or epidural needle used. Large needles (16-18G) are associated with a 70-80% risk of PDPH.(4) Early ambulation was found to have no significant association with the development of PDPH. (16) Bevel direction also found to influence the development of PDPH. (5) A study done in Nigerian in 2003-2004 revealed a 3% incidence of PDPH in obstetric patients, possibly attributed to the use of large Quincke needles. (4) Currently, there are no available data for the incidence or potential risk factors and severity for PDPH in Rwanda. The study therefore aimed at describing the incidence, risk factors and severity of PDPH in three selected hospitals in Rwanda.

1.2 Problem statement.

Post-dural puncture headache is a common side effect of neuraxial anesthesia in obstetric patients worldwide. PDPH can increase the length of hospital stay and is associated with low patient satisfaction and increased hospital readmission. Some factors known to be the causes of PDPH in

obstetric patients include the patient's weight, large gauge spinal needle, Quincke needle, multiple puncture attempt, young parturients. However, it cannot concluded or confirmed these factors in our population to be the same in our setting.

In Rwanda, less is known about incidence risk factors and severity of PDPH. The results of this study will help develop protocols for preventing and management of PDPH in obstetric patients.

1.3. The aim of the study

The aim of this study is to identify incidence, risk factors and severity of post dural puncture headache in parturients who have undergone elective or emergency Cesarean section with spinal anesthesia in three hospitals in Rwanda.

1.4. Objectives

To determine the incidence of parturient who develop PDPH after elective or emergency cesarean section under spinal anesthesia in three hospitals in Rwanda,

To determine the severity of PDPH in parturient who have undergone elective or emergency cesarean section under spinal anesthesia in three hospitals in Rwanda,

To determine risk factors associated with PDPH in parturient who have undergone elective or emergency cesarean section under spinal anesthesia in Rwanda.

1.5. Research questions

What is the incidence of PDPH among parturients who have undergone elective or emergency cesarean section under spinal anesthesia in Rwanda?

What is the severity of PDPH in parturients who have undergone elective or emergency cesarean section under spinal anesthesia in Rwanda?

What are the risk factors associated with PDPH in parturients who have undergone elective or emergency cesarean section under spinal anesthesia in Rwanda?

1.6. Operational definitions

Post dural puncture headache (PDPH): It is a headache which may occur 24 to 48 hours after spinal anesthesia or epidural anesthesia with incidental dural puncture.

Spinal Anesthesia: is a kind of neuraxial anesthesia that consist of administrating a local anesthetic into the subarachnoid space through a fine needle.

Epidural anesthetic: it is a neuraxial anesthesia which is done by injecting local anesthetic into the epidural space which surrounds the dura.

Anesthesiologist: A physician specialized in perioperative medicine, developing anesthesia plan and administration of anesthetics

Anesthesia resident: A physician who is doing specialization in perioperative medicine, developing anesthesia plan and administration of anesthetics.

Non physician anesthetist: They are anesthesia providers who have both medical and scientific knowledge and are trained to provide safe anesthesia to patients.

Non physician anesthetist Student: A personnel who is in formal training to acquire scientific and medical knowledge pertinent to anesthesia, and the skills of administering anesthesia.

CHAPTER II. LITERATURE LIVIEW

This chapter has a theoretical review that includes the anatomy of the spinal meninges, the technique of doing spinal anesthesia, spinal anesthesia for cesarean section, post-dural puncture headache definition, its pathophysiology, its signs and symptoms, its risk factors, its diagnosis, and its management and the empirical literature review related to our objectives regarding incidence,severity and risk factors of PDPH.

2.1. Theoretical review

2.1.1. Anatomy of the spinal meninges

These are three membranes which cover the spinal cord, the dura mater, arachnoid mater, and pia mater. They contain cerebrospinal fluid which plays a role of protecting the spinal cord. (13) The dura mater is essentially a tube that extends between the foramen magnum and second segment of the sacrum. It is composed of a connective tissues layer formed by elastic and collagen fibers, and it contain spinal cord and verve roots. (14) Arachnoid mater is a layer situated between the pia mater and the dura mater and both layers are separated by the subarachnoid space also containing the cerebrospinal fluid. (13)Pia mater compose the inner and thinnest layer which covers the spinal cord, nerve roots and their blood vessels. It joins the filum terminal in its distal end. The pia mater becomes thickened between the nerve roots, and it forms the denticulate ligaments. These attaches to the dura mater causing the spinal cord to be suspended in the vertebral canal. (13),(15)

2.1.2. Technique of performing spinal anesthesia

Administration of spinal anesthesia requires proper positioning of the patient and knowledge of spinal anatomy. The objective is to deliver local anesthesia into the subarachnoid space**.** For successful surgical spinal anesthesia, the practitioner needs a good understanding of the anatomy of the dermatomes and the ability to assess the level of the block once the procedure is finished. Targeted dermatomes level depends on the type of surgery. C8 dermatome is tested at the 5^{th} finger, T4 at the nipples, T7 at xphoid process and T 10 at the level of the umbilicus. (15)

2.1.3. Spinal anesthesia for Cesarean section

Spinal anesthesia is the most used anesthesia technique for elective and some emergence Cesarean section worldwide. It is simple, rapid, and cheap. However, it is associated with complications. Post dural puncture headache is one of those complications**.** (4)

2.1.4. Post dura puncture headache

Post-dural puncture headache (PDPH) is a major complication of neuraxial anesthesia that can occur following spinal anesthesia and epidural anesthesia with inadvertent dural puncture. (4)

2.1.5. Pathophysiology

PDPH pathophysiology is not fully understood but one known cause is the leakage of CSF through the hole created during dura puncture. This will lead to decreased CSF volume pressure resulting into downward pull-on sensitive structures in the brain causing PDPH. Another mechanism may be the increase in blood flow resulting from CSF loss causing cerebral arteries and venous dilation, hence PDPH. (4)

2.1.6. Signs and symptoms

Symptoms usually begin 12-24 hours post dural puncture and can rarely last up to 5 days**.** (16) PDPH can resolve spontaneously after 7 days, or it may persist up to 1 year and require pain medications. (17) The first and most common presentation of PDPH is frontal headache and is aggravated by upright position and relieved by lying down. Other symptoms include nausea, vomiting, hearing loss, tinnitus, vertigo, dizziness, visual disturbance like diplopia**.** (5)

2.1.7. Risk factors

Known risk factors of PDPH include young age because the dura become less elastic with increasing age. The increased level of estrogen in pregnant women leads to increased vessel distinstability in response to CSF hypotension hence, increased risk of PDPH. Vaginal delivery is also a known risk factor of PDPH. Pushing during the third stage of labor can increase the size of the dura hole leading to increase in CSF leak. (18) Other important risk factor is needle shape,

needle size and needle orientation during puncture. Traumatic Quincke, Greene, Hingson Ferguson, Lutz, Brace and Rovenstine needles have beveled tips that cut the dura mater whereas atraumatic needles have pencil point design. These atraumatic needles produce a separation of the tissue fibers that heals easily after removal of the needle reducing continuous CSF leak, hence low risk of PDPH. (19) Needles with large diameter result in large dura mater orifice causing increase CSF loss increasing the risk of PDPH. (18)

2.1.8. Differential Diagnosis

The differential diagnosis includes migraine, tension headache, hypertensive disorders of pregnancy, dural sinus thrombosis, ischemic and hemorrhagic stroke, meningitis, intracranial tumor, and musculoskeletal nonspecific headache drug related. (20) Postnatal depression headache, pneumocephalus, lactation headache, caffeine withdrawal, posterior reversible leukoencephalopathy syndrome. (17)

2.1.9. Diagnosis

The diagnosis of PDPH is clinical: a headache which occurs 12-24 hours post subarachnoid puncture and is characterized by the mentioned features. Brain MRI can be done to rule out other causes of headache. It can also demonstrate evidence of decreased cerebrospinal fluid pressure. (21)

2.1.10. Management of PDPH

In some cases, PDPH resolve spontaneously without treatment, but some other cases may require medical or non-medical interventions.

Conservative management

Bed rest

In most women with PDPH, their pain is relieved by bed rest. But this relieve is temporary. There is no randomized control trial which demonstrates the effect of bed rest on PDPH management. (22)

Oral fluids or intravenous fluids

It has been suggested that treating PDPH with fluid may contribute to the increase of CSF production. (22)

Abdominal binders

Abdominal binders are thought to work by increasing pressure within the spinal canal, pushing CSF cephalad, thereby reducing headache. Although one study looked at the role of abdominal binders in prophylaxis of PDPH,there are no randomized trials looking at their effect in the treatment of PDPH. (22)

Pharmacological management

Caffeine at a dose of 300-500mg orally or IV acts as cerebral vasoconstrictor and has been shown to relieve PDPH. (8) It is the treatment of choice for PDPH when simple analgesics are not effective. (4) Sumatriptan, a serotonin receptor agonist acts as cerebral vasoconstrictor and is used widely in the management of migraine, has been shown to be effective in treating PDPH. (22) However, a randomized controlled trial found no evidence to support the use of sumatriptan in the management of PDPH. (4)

Epidural blood patch

This is the gold standard treatment of PDPH, and it is done by aseptically patient's own blood, and aseptically injected it into the epidural space. The resulting clot will seal the hole caused by the dural puncture and thus will stop or diminish CSF leak. (16)

2.2. Empirical literature review

Several studies on PDPH have been conducted to determine its incidence, severity, and associated factors among the patients who have undergone obstetricoperation under spinal anesthesia. A prospective study conducted at the Aga Khan University Hospital, Nairobi found the incidence of post-dural puncture headache following emergency and elective cesarean section under spinal anesthesia to be 20.35%. The severity of the PDPD as determined by a visual analogue scale pain score found that 13% of subjects had mild pain while 48% reported moderate pain and 39% severe pain. Risk factors included preloaded vascular volume of fluid before operation, experience of anesthesia provider, the gauge of spinal needle used, the type of needle used, the number of attempts, position, and procedure duration. These risk factors were analyzed using Fisher's exact

test. Only one factor, needle type, was found to be statistically associated with the occurrence of PDPH with respect value=0.042. (23)

A prospective and observational study conducted in Togo at Sylvanus Olympio University Hospital of Lomé from April to September 2017 among 500 patients who underwent spinal anesthesia found the incidence of 6.5%. Possible associated factors were puncture level, numbers of attempts, types of procedures, age, body mass index, sex and the type of procedure. Three factors (young age, obstetrical surgery, low-to-normal BMI) were shown to increase the incidence of post dural puncture headache. (10) A cross-sectional study conducted in Ethiopia to assess magnitude of post dural puncture headache and associated factors in 391 obstetric patients who underwent spinal anesthesia for caesarean section found the incidence of 21.7%. Thirty-three percent (33%) of the participant in this study reported mild pain, 54% moderate and 11% severe pain. Risk factors included the gauge of the needle and number of attempts. (24)

A prospective study conducted at Wolaita Sodo University Teaching Referral Hospital assessed the incidence and risk factors contributing to the development of post dural puncture headache in 150 participants who underwent Cesarian section under spinal anesthesia. This study found the incidence of PDPH at 28.7%. Three factors: needle size, number of CSF drops, and multiple attempts significantly associated with the development of PDPH.(25) A randomized study in three groups conducted in Pakistan at Liaquat University hospital compared PDPH in parturients who had undergone caesarian section under spinal anesthesia by 25G Quincke, 27G Quincke and 27G Whitacre spinal needles. This study found that the development of PDPH and its severity was associated with the type of needle and its size. Through these multiple studies have differing results, the use of 27G Whitacre recommended to decrease the incidence of PDPH and its severity. (26)

CHAPTER III: METHODOLOGY

This chapter focused on how the research was conducted. It explains the research design, the area of study, population, sample, and sampling procedure, it also includes the mode of data collection and the methods we used while carrying out the research. This chapter also highlights techniques and procedures of analysis and interpretation.

3.1. Study design

A prospective study design was used to conduct this study since patient are followed up from admission until 48 hours post-C-section and looking for the outcomes in line with the study aim.

3.2. Study settings

This study was conducted in Rwanda at Kigali University Teaching Hospital and two district hospitals, Muhima District Hospital and Kibagabaga District Hospital. The University Teaching Hospital of Kigali (CHUK) is in Kigali city. It serves the city of Kigali, Northern province, part of southern and part of western provinces. Muhima District Hospital serves patients from Nyarugenge District while Kibagabaga District Hospital serves patients from Gasabo District all in Kigali city.

3.3. Study population

The population for this study comprises all mothers who have undergone elective and emergency C-section under spinal anesthesia during the period from November 2020 up to March 2021 at CHUK, Muhima District Hospital (DH) and Kibagabaga District Hospital who consented to participate.

3.4. Sampling

3.4.1. Inclusion and exclusion criteria

Inclusion criteria: All healthy pregnant mothers presenting at the Obstetric departments for elective and emergency C-section to be done under spinal anesthesia and who consent to study participation.

Exclusion criteria: Pregnant mothers presenting at the obstetric departments for elective and emergency C-section with comorbidities like hypertensive disorders of pregnancy,

chronicheadache, intracerebral pathologies, severe malaria, cardiovascular pathologies and those who did not consent to the study.

3.4.2. Sample size and sampling methods

The Sample size was calculated by using Kish (1965) of cross section studies. $N=Z^2P(1-P)/d^2$

Description:

N = Required sample size

Z= Confidence level at 95% (standard value of 1.96)

p = Estimated prevalence base on similar study conducted in Ethiopia at Dilchora Hospital and Sabian Primary Hospital was 21.7%

d = Absolute error between the estimated and true population of 5%

Calculation

N=1.96*(1.96)*0.217(1-0.217)0.05*(0.05) =261

Convenience sampling method was used for all parturients who fulfilled the inclusion criteria.

3.5. Data collection

3.5.1. Instrument description

The structured questionnairewas elaborated based on current evidence and its face validity was approved by an expert in this field , it is composed by the following variables: patients age, BMI, history of previous cesarean section under spinal anesthesia, history of PDPH for the previous C-section, size of spinal needle, numbers of attempts, experience of the anesthesia provider, complications post the current spinal (headache, neck pain), PDPH presence and its characteristics, pain score (mild, moderate and severe), treatment required including medications, and hospital readmission and puncture attempt. Numeric pain score was used to grade the severity of PDPH.

3.5.2. Data collection procedure

Three research assistants were trained by the main author to explain to them the purpose of the study, the questionnaire for data collection, different terminologies on the questionnaire, the process of collecting information which was to start on the visit of the patient before entering the operating theater, intraoperative information and following them at 24-48 hours postoperatively for data collection. Before starting data collection, research assistants were presented to the in-charge of anesthesia in the obstetric department in each of the three hospitals to facilitate them during the process of intraoperative data collection. They were also shown where to meet patients postoperatively by using the recovery register which shows the locations of patients who underwent C-sections. we collected data together within the first three days (one day for each hospital) to make sure the questionnaire is being filled efficiently. The Author had to visit each hospital once a week to meet these assistants to make sure they were collecting data accurately, to collect the filled questionnaire, and to make sure there is no problem being faced during this process of data collection.

Before collecting information from the parturients, the purpose of the study was explained, and obtaining informed consent, the parturient demographics and relevant past medical histories were recorded. Intraoperatively, the size and the type of needle were recorded. The number of puncture attempts before entering subarachnoid space and administration of anesthesia were recorded. The participants were followed post-operatively at 24 hours and at 48 hours to assess the development of PDPH, its relieving or aggravating factors, and the management. The severity of PDPH was assessed by using a numeric rating scale**.**

3.6. Data analysis

Data collected were coded and entered excel sheet and were imported into SPSS version 23, IBM for analysis. Descriptive statistics were used to display the frequency, percentages, and proportion for categorical variables. To identify risk factors associated with the development of PDPH, each independent variable and the dependent variable were analyzed busing binary regression and were considered as significant if their P value is<0.2. Variables were entered into multivariate logistic regression with the identification of the confounds. On a multivariate logistic regression model, the significant risk factor had P value less than 0.05.

3.7. Ethical consideration

The primary investigator obtained the ethical clearance No 009/CMHS IRB/2020 from the Institutional Review Board of the College of Medicine and Health Science (IRB/CMHS) and requested permission to conduct research at CHUK, Muhima DH and Kibagabaga DH. To ensure anonymity and confidentiality of participants, codes were used on questionnaires and kept in a locked box. All pregnant mothers or their caregivers were informed about the study before they are asked to participate. Data obtained were used only for this study and were kept confidential. The participants were informed that refusal to participate or withdrawal from the study would not result in penalty or affect treatment.

3.8. Data management

All data collected were coded, imported into SPSS, and stored safely and confidentially on the researcher's personal password-controlled computer, online driver with the research purpose only. Hard data were locked in a cupboard of the primary investigator.

3.9. Data dissemination

The results of this study will be published to be accessible to the academic, other researchers and healthcare provider as needed. The primary investigator will also provide feedback based on the finding to the study settings which will help them to set the way forward to develop the guideline and protocol regarding the management and prevention of post dural puncture headache to improve the quality of care.

3.10. Limitation of the study

The participants were followed post operatively at 24 hour and at 48 hours to assess the development of PDPH, this may have missed the participant who develop PDPH after 48 hours. This study was unable to assess the effect of different size and type of the needle on the development of post dural puncture because there was only one size of needle and one type used in all three hospitals.

CHAPTER IV: RESULTS

This chapter covers the presentation of the findings which is presented in table or figures and the summary of the content within the table.

4.1. Demographics characteristics

A total of 261parturients were recruited in this study.

Table 1: Social demographic characteristics

Variables		**Frequency: N (%)**
Age	Less than 20 years	12(4.6)
	Between 20-29 years	106(40.6)
	Between 30-39 years	134(51.3)
	Greater than or equal 40years	9(3.4)
Body Mass Index	Underweight: <18.5	
	Normal :18.5-24.9	154(59)
	Overweight:25-29.9	98(37.5)
	Obese:30-34.9	9(3.4)

Over half of them 134(51.3%) ranged between 30-39 years of age while only 9(3.4%) were greater than or equal to 40 years. Over half 154(59%) had BMI within the normal range for weight and height. No participant was underweight but 98(37.5%) were classified as overweight based on BMI.

Table 2: Indication of previous and current cesarean section

Indications	**Frequencies (%) of previous indication**	**Frequencies (%) of current indication**
1. Previous scar	75(28.7)	111(42.5)
2. Failed induction	39(14.9)	25(9.6)
3. Maternal request	10(3.8)	5(1.9)
4. Fetal distress	30(11.5)	60(23.0)
5. Placenta Previa	7(2.7)	4(1.5)
6. Twin pregnancy	14(5.4)	7(2.7)
7. Arrested labor	21(8.0)	6(2.3)
8. PPROM	13(5.0)	5(1.9)
9. Breech presentation	22(8.4)	20(7.7)
10. Fetal malformation	3(1.1)	1(0.4)
11. Fetal macrosomia	4(1.5)	8(3.1)

12. Oligohydramnios	8(3.1)	3(1.1)
13. Fetal demise	1(0.4)	2(0.8)
14. Fetal macrosomia	3(1.1)	1(0.4)
15. Cord prolapse	4(1.5)	1(0.4)
16. CPD (cephalopelvic disproportion)	7(2.7)	2(0.8)

As shown in table2, higher prevalence of previous scar as C section indication was observed at rate 28.7% in previous C sections and at the rate of 42.5% in current C-section. Failed induction and fetal distress were frequent indications for previous cesarean section with respective frequencies of 39(14.9%) and 30(11.5%). Currently, both failed induction and fetal distress were also frequent indications for C section, with the rate of 23.0% for fetal distress and 9.6% for failed induction. Rarely, fetal macrosomia and fetal malformation were the indications of cesarean (1.1%) in previous cesarean section. Currently, fetal macrosomia, fetal malformation and cord prolapse were observed as the indications of cesarean section at the same rate of 0.4%.

Previous pain characteristics

Twenty-point four percent (20.4%) of the parturients reported post dural puncture headache in the previous cesarean section. 32.8% reported PDPH to be severe, 31.1% reported to have had mild PDPH and 41.6% of the parturients required pain medication. Only 6.3% required readmission for further management. See Table 3

Table 3: Previous pain characteristics

Variables		**Frequencies (%)**
PDPH		53(20.4)
Severity	Mild	17(32.1)
	Moderate	22(41.5)
	Severe	14(26.4)
The one who required pain medication		37(41.6)
The ones who required hospital readmission		6(6.3)

Before spinal anesthesia administration more than a half, 53.6% of parturients were hydrated with intravenous fluid, 20.3% received oral fluids and 26.1% did not receive any hydration fluid. We were unable to quantify the volume of fluid taken orally because most of the patient were unable to report the volume taken. However intravenous volume was reported, 27.6 % (72) received 500cc of normal saline while 26.1 % (68) received 1000cc.More than half 59.8% of spinal anesthesia was administered by non-physician anesthetists. In all hospitals, we did not observe any anesthesiologist administer spinal anesthesia during our data collection period. See table 4

Table 4: Spinal anesthesia procedure characteristics

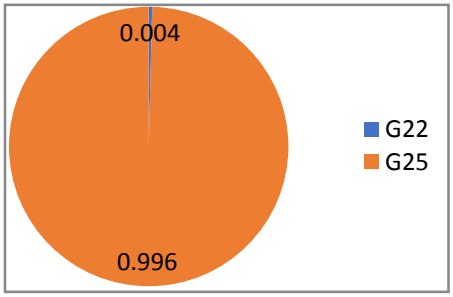
Variables		**Frequency (%)**
Hydration prior to anesthesia	IV Fluid	140(53.6)

	Volume of Fluid given	500cc	72(27.6)
		1000cc	68(26.1)
	Oral fluid		53(20.3)
	None		68(26.1)
Level of the anesthesia provider	Anesthesiologist		0(0)
	anesthesia resident		35(13.4)
	non-physician anesthetist		156(59.8)
	non-physician anesthetist student		70(26.8)
Baricity of local anesthetic	Isobaric		5(1.9)
	Heavy		256(98.1)
Dose of local anesthetic	10mg		261(100)
Size of the spinal needle used	G22		1(0.4)
	G25		260(99.6)
Shape of the spinal needle	Quincke		261(100)
	pencil point		0(0)
Number of puncture attempts	One attempt		136(52.1)
	Two attempts		125(47.9)

	More than two attempts	0(0)

In regard to the medication used, almost all the parturients, 98.1% received hyperbaric local anesthesia at the dose of 10mg. The size of needle most frequently used was G25, (99.6%). Quincke needles were exclusively used. More than a half of participants, 52.1%, had successful anesthesia administered with one attempt, no more than two attempts were recorded. See fig 1

Figure 1: The number of each gauge needle used



4.2. Incidence

Almost the same incidence was found in the district hospitals. The results of this study revealed 38.7% at Muhima District Hospital and 37.07% at Kibagabaga District Hospital. However, University Teaching Hospital of Kigali (CHUK) showed an incidence of 21.62%. See table 5

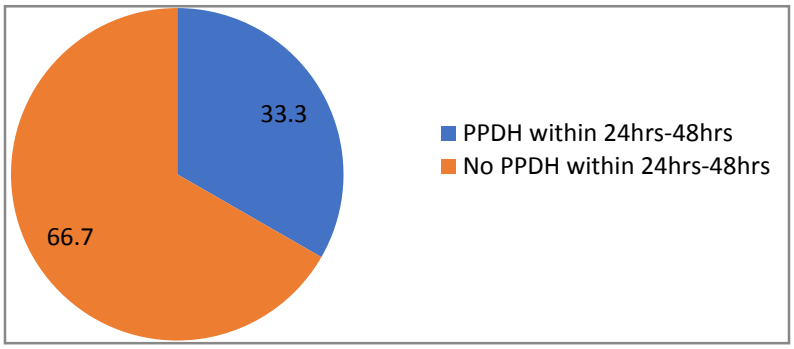
Table 5: Incidence to each selected hospital

Hospitals	CHUK	MUHIMA DH	KIBAGABAGA DH
Parturients	74	98	89

Incidence (%)	16(21.62)	38(38.77)	33(37.07)

The results showed the overall cumulative incidence of post dural puncture headache which is 33.3 in three selected hospitals. See Fig 2

Figure 2: Overall incidence in all selected hospital



4.3 Severity of PDPH and its characteristics

Current pain characteristics

Fifty four percent (54%) of the parturients reporting PDPH also reported neck pain. In most participants, 78.2%, with PDPH the pain was aggravated by upright position and relieved by lying flat at the same rate. 47.1% of the parturient received pain medication but some relief of pain was not accomplished by medication. The medication improved the condition at the rate of37.9%.The greater portion according to the severity of PDPH was 44.8% which is moderate and the small portion of16.1% was severe. See table 6

Table 6: Current pain characteristics

Variables	**Frequency N (%)**

neck pain	Yes	47(54)
	No	40(46)
aggravated by upright position	Yes	68(78.2)
	No	19(21.8)
relieved by lying flat	Yes	68(78.2)
	No	19(21.8)
receive medications for that headache	Yes	41(47.1)
	No	46(52.9)
Medications improve your condition	Yes	33(37.9)
	No	54(62.1)
Severity of headache	Mild	34(39.1)
	Moderate	39(44.8)
	Severe	14(16.1)

4.4. Associated factors to the development of PDPH

Binary logistic regression of independent with dependent variable (PDPH)

Univariate analysis of age, hospital, number of puncture attempts, size of the spinal needle used, and indication of the current cesarean section were not significantly associated with the occurrence

of outcome variable (PDPH) with the following P-values, 0.626, 0.71, 0.324, 1.000, 0.262 respectively at a significant p-value less than 0.2. Body mass index, hydration prior to anesthesia, experience of the anesthesia provider, and PDPH after the previous cesarean section were significantly associated with the occurrence of outcome variable at p-value less than 0.2. These variables were then introduced into multivariate logistic regression to mitigate co-founding effects.

Table7: Binary logistic regression of independent with dependent variable (PDPH)

Independent variables	**P-Values**	**95% C.I.**	
		Lower	**Upper**
BMI	.000	.409	.094
Age	.626	1.494	.513
Hospital	.711	1.544	.529
Number of puncture attempts	.324	1.411	.352
Size of the spinal needle used	1.000	.000	.000
Hydration prior to anesthesia	.008	.769	.167
Level of the anesthesia provider	.010	.812	.213
PDPH after the previous cesarean section	.024	5.795	1.135
Indication of the current cesarean section	.262	1.027	.854

Table 8: Multivariate Analysis of BMI, Hydration prior to anesthesia, Level of the anesthesia provider and PDPH after the previous cesarean section

	Coefficient		**95% C.I.**

Valuables		**P-values**	**Lower**	**Upper**
Normal body mass index :18.5-24.9 $kg.m^{-2}$	1.435	.000	2.248	7.845
Anesthesia resident	-2.302	.003	.022	.453
Hydration prior to anesthesia by intravenous fluid	-.997	.007	.178	.766
PDPH after previous cesarean section	.820	.036	1.054	4.891

Low to normal body mass index: 18.5-24.9 $kg.m^{-2}$, Anesthesia resident, hydration prior to anesthesia by intravenous fluid, PDPH after previous cesarean section were statistically significant associated with the occurrence of PDPH with respective P values 0.000; 0.003; 0.007; and 0.036. As multivariate coefficient for hydration with intravenous fluid and anesthesia resident providing spinal anesthesia are negative, it means that they are associated decrease occurrence of PDPH while the positive coefficient for BMI low to normal and previous history of PDPH means that they are associated withincreased occurrence of PDPH.

CHAPTER V: DISCUSSION

5.1. Incidence

Over the period of five month from November 2020 to March 2021, this study found an overall cumulative incidence of PDPH at 33.3%. The results are similar to 2 studies conducted in Ethiopia and Egypt. (25)(27) These studies found an incidence of 28.7% and 33% of PDPH respectively. This similarity may be due to the similarities in hospital settings in the developing countries. However, a study conducted in Kenya to assess incidence, risk factor and severity of PDPH showed a higher incidence of 47.5%. (28) This difference may be due to the different period of time in which these studies were conducted. As medicine, especially anesthesia improves day by day, it may justify the higher incidence in study conducted in 2009 compared to the study conducted after 2014.

In contrast different studies showed low incidence when compared to the aforementioned. A study conducted in Togo, a low-income country like Rwanda where the Quincke needle is used and there is a shortage of trained anesthesia providers and limited medical equipment and consumables. In this study a lower incidence of 6.5% was found. (10) This conflicting difference may be due to the different exclusion criteria, here parturients who were in need of emergence cesarean section and those who had the history of PDPH were excluded from the study. Further studies are needed to affirm the justification. A retrospective analytical study conducted in Jordan to assess the risk factors of PDPH among women who underwent cesarean section using spinal anesthesia also found the lower incidence of 6.3%. (29) This difference may be justified by the low percentage of parturients who were given spinal anesthesia by using Quincke needle. In our study a hundred percent received the anesthesia by using Quincke needle.

5.2. Severity of post dural puncture headache

The results of this index study showed that 44.8% of PDPH was considered moderate, 39.1% mild and only 16.1% were reported as severe. The severity was based on pain score where no pain was scored 0/10 mild pain was scored from 1-3/10, moderate pain was scored from 4-6/10 and severe pain scored from 7-10/10 using numeric pain score.

The severity of PDPH observed in our study is very similar to different studies which showed the mild to moderate PDPH as the most frequently reported and rarely reported as severe. (24), (28) (30), (31), (32)

5.3.Risk factors

The results of this study found that a body mass index of 18.5-24.9 $kg.m^{-2}$or lower, anesthesia resident, hydration with intravenous fluid prior to anesthesia, and PDPH after previous cesarean section were statistically significantly associated with the occurrence of PDPH. Normal body mass index has previously been shown to increase the risk of developing PDPH. (33)(34) One possible explanation is that the parturient who is obese may have intra-abdominal pressure and aid in sealing the defect resulting from the dural puncture. There by reducing the loss of CSF. (5) However, other studies fail to demonstrate the effect of BMI on the on the development of PDPH. (25)(31)(35) This study found that the decrease in development of PDPH is statistically significant related to the qualification of the anesthesia provider. This is similar the Ethiopian study. (14) Other studies did not find significant effect of anesthesia provider qualification on the development of PDPH. (23), (36)

The finding of the presentstudy showed that adequate hydration prior to anesthesia by intravenous fluid is significantly associated with the reduction of PDPH occurrence. This is complementary to assumption which says that oral hydration can increase CSF production and thereby prevent the occurrence of PDPH. However, this assumption, it has not been statistically significantly demonstrated. (37) As it is demonstrated in this study, hydration through intravenous prior to lumber puncture showed the decrease in incidence of PDPH in randomized control trial conducted at neurology clinic. (38) PDPH after previous C/section was also found in this study to increase the incidence of PDPH. These findings are similar to the study conducted in Israel which showed a history of PDPH can significantly increase the incidence of PDPH. (39) Similarly, a study conducted in Brazil confirmed that prior PDPH is a risk factor for resultant PDPH. 40 The number of puncture attempts and the size of needle used were not significantly associated with the occurrence of PDPH in this study. In other different studies these were the most influencing factors. (7),(25), (29) ,(30), (32), (41),(42), (43),(44),(45) This difference may be due the use of uniformly sized needles where in all hospitals one size of

needle 25G was used and the absence of more than two puncture attempts in our study. Different studies conducted in different countries with different designs revealed that the type of needle used is the frequent risk factors for developing post dural puncture headache. (12), (23) ,(29),(46) (47),(48),(49),(50)

CHAPTER VI: CONCLUSION AND RECOMMENDATIONS

This chapter presents the overview of the findings of incidence, risk factors, and severity of post-dural puncture headache in patients who underwent Cesarean section in three hospitals in Rwanda. It presents the conclusion and recommendations of the study findings.

6.1. Conclusion

A high incidence (33.3 %) of post dural puncture headache was found among 261 parturients who were recruited in this study. The severity of this PDPH ranged from mild to moderate and rarely severe. Moreover, body mass index below 25 $kg.m^{-2}$ and PDPH after previous Cesarean section were statistically significantly associated to the increase of PDPH occurrence with respective p values of 0.000 and 0.036.

6.2. Recommendations

The ministry of health and health facilities are recommended to increase training of anesthesia providers in district hospitals and even in referral hospitals.

The hospital management are advised to provide other than Quincke needles. Pencil point spinal needleswhich are known to be associated with to decrease the incidence and severity of PDPH.

Further studies are needed to identify other possible risk factors, their confounding and modifying effects, to look on the effect of IV fluid administration prior to spinal anesthesia on the development of PDPH in our settings

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APPENDIXES

1. CONSENT FORM

INFORMATION SHEET AND CONSENT FORM for the study entitled **"Incidence, risk factor and severity of postdural puncture headache in three hospital in RWANDA"**
AMAKURU N'ICYEMEZO CYO KUGIRA URUHARE MU BUSHAKASHATSI
Researcher identification:
Umwirondoro w' umushakashatsi

UWIHOREYE CLEMENTINE, MD, Resident in Anesthesia at the University of Rwanda.
UWIHOREYE CLEMENTINE, Umuganga uri kwiga gutanga ikinya muri Kaminuza y'u Rwanda

Purpose of the Research project:
Impamvu y'ubushakashatsi

Is to identify incidence, risk factors and severity of post Dural puncture headache in patients who underwent elective and emergency cesarean section in three hospitals in RWANDA (KIGALI UNIVERSITY TEACHING HOSPITAL, MUHIMA DISTRICT HOSPITAL AND KIBAGABAGA HOSPITAL).

Ubu bushakashatsi bugamije kureba ingano y'ababyeyi barwara umutwe uturuka kuguterwa ikinya cyo mumugongo nyuma yo kubagwa babyara ,ibitera ndetse n'ubukana bw'uwo mutwe mubitaro bikuru bya Kaminuza y'URWANDA (CHUK),ibitaro by'Akarere bya MUHIMA ndetse n'Ibitaro by'Akarere bya KIBAGABAGA.

How long will I take part of this research?
Igihe ubushakashatsi buzamara
The study will take around 6 months.
Ubushakashatsi buzamara amezi 6.

Benefits, Risk or Discomfort

Ibyago n'inyungu zo kuba muri ubu bushakashatsi

There will be no direct benefit to study participants. But the result of this study will be used for further improvement of the service. There will be no risk of participating in this study.

Nta nyungu z'ako kanya uzabona muri ubu bushakashatsi, ariko amakuru y'ubu bushakashatsi azakoreshwa mu kunoza serivisi duha abarwayi. Nta byago duteganya igihe waba uri muri ubu bushakashatsi.

Participation is voluntary
Kwitabira ni ku bushake

Confidentiality:

Ibanga:

The information collected from the study subjects will be kept confidential and by assigning a code number to each patient, the name of the patient will not be recorded or used in any report.

Amakuru yose utanga muri ubu bushakashatsi azagirwa ibanga. Ayo makuru azahabwa inumero y'ibanga. Nta hantu na hamwe amazina y'umurwayi azakoreshwa.

Right to refusal or withdraw

Igihe wahagarikira uruhare rwawe muri ubu bushakashatsi**:**

Study subjects will have full right to refuse from participating in this research without penalty.

Ushobora guhagarika uruhare rwawe muri ubu bushakashatsi igihe icyo aricyo cyose kandi ntubiryozwe.

Persons to contact
For any questions or concerns you can contact the principal investigator or senior mentor using the following addresses:

Niba ufite ibibazo bijyanye n'ubu bushakashatsi, binyuze kuri aba bakurikikira*:*

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Or

The chairperson of the CMHSIRB: 0788490522

STUDY SUBJECTS CONSENT FORM

Kwemera kugira uruhare mu bushakashatsi

As a patient or caregiver of this patient, I agree to take part in this study described above.

Nk'umurayi cyangwa undi muntu uhagarariye uyu murwayi, ndemera kugira uruhare muri ubu bushakashatsi nasobanuriwe.

Patient/Caregiver'ssignature : _____Date:_____

Umukono w'umurwayi/Umuhagarariye : _____ Itariki : ___

2. QUESTIONNAIRE

Data collection tool

Id number:

Patient's age:

Parity:

Weight:

Height:

Past medical history

1. Any previous delivery by cesarean section under spinal anesthesia? Yes◯/no◯

If yes:

Indication of that cesarean section.

Did you have headache or neck pain after that previous cesarean section?

yes◯/no◯

If yes, how severe was that headache?

Mild ◯moderate ◯ severe◯

Did it require medication? yes◯ no◯

Did it require hospital readmission yes ◯ no ◯

Concerning the current pregnancy and delivery

1. Indication of the current cesarean section:

2. Hydration prior to anesthesia IV fluid ◯ oral fluid ◯

3. Quantity of IV fluid: 500ml ◯ 1L ◯ above 1L ◯

4. Level of the anesthesia provider: Anesthesiologist◯ anesthesia resident◯ non-physician anesthetist ◯ non-physician anesthetist student ◯

5. Baricity of local anesthetic drug given isobaric◯ heavy◯

6. Dose of local anesthetic

7. Size of the spinal needle used? G22 ◯ G25 ◯

8. Shape of the spinal needle: Quincke ◯ pencil point ◯

9. Number of puncture attempts. 1 ◯ 2 ◯ more than 2 ◯

24-48 hours post-operative:

1. Did you have any headache in these 24hrs after your spinal yes ◯ no ◯

Neck pain yes ◯ no◯

Is it aggravated by upright position yes ◯ / no ◯

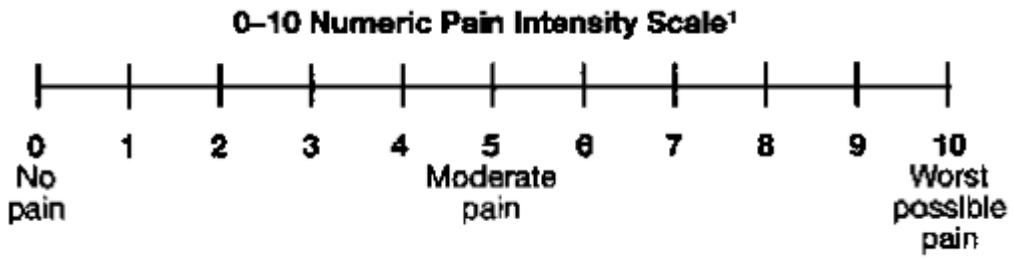
Is it relieved by lying flat yes ◯ no ◯

2. Did you receive medications for that headache yes ◯ no◯

3. If yes, did it improve your condition? Yes ◯ no◯

4. How severe is that headache? Mild ◯ moderate ◯ severe ◯

This will be assessed using WHO pain scale below. (Please circle your estimation of the severity of your pain)



3. IRB APPROVAL

UNIVERSITY of RWANDA

COLLEGE OF MEDICINE AND HEALTH SCIENCES

DIRECTORATE OF RESEARCH & INNOVATION

CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, 23rd January 2020

Dr UWIHOREYE Clementine
School of Medicine and Pharmacy, CMHS, UR

Approval Notice: No 009/CMHS IRB/2020

Your Project Title ***"Incidence Risk Factors and Severity of Post Dural Puncture Headache In Three Hospitals In RWANDA"*** has been evaluated by CMHS Institutional Review Board.

		Involved in the decision		
			No (Reason)	
Name of Members	**Institute**	Yes	**Absent**	**Withdrawn from the proceeding**
Prof Kato J. Njunwa	UR-CMHS		X	
Prof Jean Bosco Gahutu	UR-CMHS	X		
Dr Brenda Asiimwe-Kateera	UR-CMHS	X		
Prof Ntaganira Joseph	UR-CMHS	X		
Dr Tumusiime K. David	UR-CMHS	X		
Dr Kayonga N. Egide	UR-CMHS	X		
Mr Kanyonu Maurice	UR-CMHS		X	
Prof Manyanshongore Cyprien	UR-CMHS	X		
Mrs Ruzindana Landrine	Kicukiro district		X	
Dr Gisihoma Darius	UR-CMHS	X		
Dr Donatilla Mukamana	UR-CMHS	X		
Prof Kyamanywa Patrick	UR-CMHS		X	
Prof Condo Umutesi Jeannine	UR-CMHS		X	
Dr Nyirazinyoye Laetitia	UR-CMHS	X		
Dr Nkeramihigo Emmanuel	UR-CMHS		X	
Sr Mukiholi Marie Josee	CHUK	X		
Dr Mudenge Charles	Centre Psycho-Social	X		

After reviewing your protocol during the IRB meeting of where quorum was met and revisions made on the advice of the CMHS IRB submitted on 21st January 2020, **Approval has been granted to your study**.
Please note that approval of the protocol and consent form is valid for **12 months**.

You are responsible for fulfilling the following requirements:

1. Changes, amendments, and addenda to the protocol or consent form must be submitted to the committee for review and approval, prior to activation of the changes.
2. Only approved consent forms are to be used in the enrolment of participants.
3. All consent forms signed by subjects should be retained on file. The IRB may conduct audits of all study records, and consent documentation may be part of such audits.
4. A continuing review application must be submitted to the IRB in a timely fashion and before expiry of this approval
5. Failure to submit a continuing review application will result in termination of the study
6. Notify the IRB committee once the study is finished

Sincerely

Date of Approval: 23rd January 2020

Expiration date: The 23rd January 2021

Professor GAHUTU Jean Bosco
Chairperson Institutional Review Board
College of Medicine and Health Sciences, UR

Cc:
- Principal College of Medicine and Health Sciences, UR
- University Director of Research and Postgraduate Studies, UR

1. Turnbull DK, Shepherd DB. Post-dural puncture headache: Pathogenesis, prevention and treatment. Br J Anaesth [Internet]. 2003;91(5):718–29. Available from: http://dx.doi.org/10.1093/bja/aeg231