PREVALENCE OF POST DURAL PUNCTURE HEADACHE AND ASSOCIATED FACTORS IN MOTHERS FOR ELECTIVE CESAREAN SECTION AT MUHIMBILI NATIONAL HOSPITAL

Hakim Stephen Cizario Odu, MBBS

MMed (Anaesthesiology) Dissertation
Muhimbili University of Health and Allied Sciences
October, 2017

Muhimbili University of Health and Allied Sciences

Department of Anaesthesiology

PREVALENCE OF POST DURAL PUNCTURE HEADACHE AND ASSOCIATED FACTORS IN MOTHERS FOR ELECTIVE CESAREAN SECTION AT MUHIMBILI NATIONAL HOSPITAL

By

Hakim Stephen Cizario Odu

A Dissertation/ Thesis Submitted in (partial) Fulfillment of the Requirement for the Degree of Master of Science (Anaesthesiology) of

Muhimbili University of Health and Allied Sciences
October, 2017

CERTIFICATION

The undersigned certify they have read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled; ***"Prevalence of post dural puncture headache and associated factors in mothers for elective cesarean section at Muhimbili National Hospital'',*** in (partial) fulfillment of the requirements for the degree of Master of Medicine (Anaesthesiology) of Muhimbili University of Health and Allied Sciences.

_____

Dr. Frederic Mbanga

Supervisor

_____

Date

_____

Dr. Karima Khalid

Co- Supervisor

_____

Date

DECLARATION

AND

COPYRIGHT

I, **Hakim Stephen Cizario Odu**, declare that, this **dissertation** is my original work and that it has not been presented and will not be presented to any other University for similar or any other degree award.

Signature……**Date**…….

This dissertation is a copyright material protected under the Berne Convention, the Copyright Act 1999 and other international and nation enactments, in that behalf, on intellectual property. It may not be reproduced by any means, in full or part, except for short extracts in fair dealing, for research or private study, critical scholarly review or discourse with acknowledgement, without the written permission of the Directorate of Postgraduate Studies, on behalf of both the author and the Muhimbili University of Health and Allied Sciences, Dar es Salaam, Tanzania.

ACKNOWLEDGEMENTS

I would like to express my humble gratitude to the Almighty God for his abundant blessings and guidance throughout the whole period of my postgraduate study.

I am humbled and so grateful to my supervisor Dr Fredric Mbanga Senior Lecturer in department of Anesthesia, MUHAS, for the continuous guidance and timely tireless constructive inputs from the initial stages of proposal development to the writing of the final stages of the dissertation report. Special thanks to Dr Karima Khalid, a lecturer in department of anesthesia, MUHAS, for co-supervising this work; her dedicated involvement at each stage in hand with tireless provision of necessary corrections and additions was very significant.

I thank the entire staff of the department of Anesthesiology, and all staff members in obstetric maternity theatre of MNH, for giving me all necessary cooperation during the process of data collection. The same goes to my research assistants; Dr Andrea and Dr Moses, for their hard work and tireless to and fro trips from theatre and maternity ward gathering the necessary information for completion of this dissertation. I would like to thank the Ministry of Health in collaboration with UNFPA for sponsoring me throughout the study.

I would like to thank my senior colleague Dr Charles Ochero Cornelio Langoya for assisting me in various stages of this dissertation.

My special thanks are to my lovely wife Gune Tongun Ladu for inspirational support and understanding and tolerating my busy academic schedules, I have no words to express my gratitude. Her prayers, day to day support and encouragement kept me going throughout the entire study period, making a seemingly hard job look simple and easy to accomplish.

Finally, I would like to extend my thanks to all my relatives and friends who supported me in many different ways.

DEDICATION

This dissertation is dedicated to my beloved parents, my father Rev. Cizario Odu Hakim and my mother Mrs. Asunta Sadia; I could not have done this without your faith, support and constant encouragement. Thank you for teaching me to believe in God, in myself and in my dreams and here I am making another step in my life.

To all my teachers; it is by their guidance and everlasting commitment towards training me that I have reached this stage.

ABSTRACT

Background

Neuraxial anesthesia is still the key note of regional blockade; it is popular for its effectiveness in producing anesthesia and analgesia. Post dural puncture headache occurs as the cerebrospinal fluids leaks out from the breach that the needle has made in the dura during administration of spinal anesthesia. PDPH is a common complication after spinal anesthesia(1). However spinal anesthesia is one of the routinely done procedures in practice.

Broad objective

To assess the magnitude of post dural puncture headache and associated factors after spinal anesthesia among patients at Muhimbili National Hospital.

Study Design

Hospital based cross sectional study

Study Population

All patients undergoing elective caesarean section under spinal anesthesia during the study period.

Study setting

The study was conducted at MNH, Dar es Salaam at the maternity theater and maternity ward.

Data Collection

A data collection form was used to collect data from all eligible patients included in the study period, who came for elective cesarean section under spinal anesthesia at MNH. Patients were interviewed and their chart reviewed at 24 hrs, 48hrs and 72 hrs, postoperatively by the principle investigator.

Data Analysis

Data collected was coded, entered in computer and managed in Microsoft access database. It was analyzed using SPSS version 20 and presented in tables and graphs. All variables were categorized and described using frequency distribution. Bivariate association was described using chi- square test, a p –value of < 0.05 was considered statistically significant.

Results

Out of 276 mothers undergoing spinal anesthesia for elective cesarean section the prevalence of PDPH was found to be higher 56% among patients who developed PDPH. Multiple dural puncture attempts were significantly related to PDPH (P value ≤ 0.001). While younger age is susceptible to developed PDPH. Out of the 154 mothers who developed PDPH, 124 had other symptoms associated with PDPH.

Conclusions and Recommendations

The prevalence of PDPH was found to be higher in MNH. The hospital management and the anesthetists in the hospital should minimized the prevalence of PDPH by avoiding multiple dural puncture and encourage single attempt during training of residents.

TABLE OF CONTENTS

CERTIFICATION i
DECLARATIONANDCOPYRIGHT ii
ACKNOWLEDGEMENTS iii
DEDICATION iv
ABSTRACT v
TABLE OF CONTENTS vii
LIST OF TABLES ix
LIST OF FIGURES x
LIST OF ABBREVIATIONS xi
DEFINITION OF TERMS xiii
CHAPTER ONE 1
1.0 INTRODUCTION AND LITERATURE REVIEW 1
1.1 Introduction 1
1.2 Literature Review 3
1.3 Conceptual Framework 6
1.4 Problem Statement 8
1.5 Rationale 9
1.6 Research Question 10
1.7 Objectives 10
1.7.1 Specific Objectives 10
CHAPTER TWO 11
2.0 METHODOLOGY 11
2.1 Type of Study 11
2.2 Study Area 11
2.3 Study duration 11
2.4 Study population 11
2.4.1 Inclusion Criteria 11
2.4.2 Exclusion Criteria 12

2.5 Patients Involved 12
2.6 Sample Size Determination 12
2.7 Procedures and Data Collection 13
2.8 Data Analysis 15
2.9Ethical Clearance 15
2.10 Study Limitations 15
2.11 Dissemination of Results 15
CHAPTER THREE 16
3.0 RESULTS 16
CHAPTER FOUR 22
4.0 DISCUSSION 22
CHAPTER FIVE 26
5.1 Conclusion 26
5.2 Recommendations 26
REFERENCES 27
APPENDICES 31
Appendix 1: Criteria of post dural puncture headache diagnosis: 31
Appendix 2: Table (1) headache severity. 32
Appendix 3: American society of anaesthesiologist (ASA) physical status classification. 33
Appendix 4: Quality of evidence ratings for therapeutic modalities. 34
Appendix 5: Data sheet form (Questionnaire) Adopted from Samuel M et al, 2009(31). 35
Appendix 6: Consent Form - English Version 37
Appendix 7: Consent Form - Swahili Version 40

LIST OF TABLES

Table 1: Distribution of participant's age group……..16

Table 2: Distribution of anesthesia provider, anesthetic experience and indication for procedure……..17

Table 3: Frequency distribution of quantity of intravenous fluid, needle orientation and number of dural puncture attempts……...18

Table 4: Distribution of PDPH with anesthesia provider, experience, number of Dural puncture attempts…….....20

Table 5: Distribution of PDPH with duration of surgery, orientation of the needle and IV fluid therapy……21

Table 6: Frequency distribution of symptoms associated with PDPH ……22

LIST OF FIGURES

Figure 1: Distribution of PDPH among participants……...…..18

Figure 2: Percentage distribution of PDPH onset among participants……..19

LIST OF ABBREVIATIONS

ARD	Acute Respiratory Distress
ASA	American Society of Anesthesiologists
BMI	Body Mass Index
C/S	Caesarean Section
CAD	Coronary Artery Disease
COPD	Chronic Obstructive Pulmonary Disease
CPD	Cephalopelvic Disproportion
CSF	Cerebral Spinal Fluid
CVA	Cerebrovascular Accident
DIC	Disseminated Intravascular Coagulation
DM	Diabetes Mellitus
EBP	Epidural Blood Patch
ESRD	End Stage Renal Disease
G	Gauge
Hrs	Hours
HTN	Hypertension
ICU	Intensive Care Unit.
IV	Intravenous
MI	Myocardial infarction
mLs	Milliliters
MNH	Muhimbili National Hospital

MRI	Magnetic Resonance Imaging
MUHAS	Muhimbili University of Health and Allied Sciences.
NSAIDS	Non-steroidalanti-inflammatory drugs
PCA	Post Conceptual Age
PDPH	Post Dural Puncture Headache
SPSS	Statistical package for social sciences
TIA	Transient Ischemic Attach
UNFPA	United Nation Population Fund
USD	United State Dollar

DEFINITION OF TERMS

CSF: Is a clear colorless liquid in the brain and spine produced in the choroid plexuses of the ventricles of the brain. It acts as a cushion or buffer for the brain's cortex, providing basic mechanical and immunological protection to the brain inside the skull.

Spinal anesthesia: Spinal anesthesia is induced by injecting small amounts of local anesthetics into the cerebrospinal fluids.

Big spinal needle: A needle size that include 18G, 20G or 22G.

Small spinal needle: A needle size that include 24G, 25G or 27G.

Single attempt: Spinal anesthesia was successful at first attempt.

Multiple attempts: Two or more attempts were performed before successful spinal anesthesia.

Spinal dura matter: Spinal dura matter is a tube extending from the foramen magnum to the second segment of the sacrum. It contains the spinal cord and nerve roots that pierce it.

CHAPTER ONE

1.0 INTRODUCTION AND LITERATURE REVIEW

1.1 Introduction

Post dural puncture headache (PDPH) is a common complication after lumbar puncture. Although many physicians (radiologist, neurologist, paediatricians, and internal medicine and emergency specialist) perform lumbar punctures, anaesthesiologists and pain physicians are the most likely to be consulted for the treatment of PDPH(2). The presence of PDPH can be debilitating for a patient and can significantly interfere with functional capacity (e.g. activities of daily living) and quality of life. The diagnosis and treatment of PDPH poses many challenges for the anaesthesiologist and pain physician. Despite the relatively straight forward diagnosis of PDPH in many cases, other etiologies may mimic or coexist with the condition(2).

PDPH is an important iatrogenic cause of patient morbidity in modern day anesthesia and pain management practice after attempted epidural blocks and after spinal taps(3). Dural puncture is a commonly performed invasive procedure for various indications like diagnostic lumbar puncture, spinal anesthesia, myelography and intrathecal chemotherapy(4). However, in anesthesia practice apart from intentional dural puncture as in spinal anesthesia, unintentional dural puncture can also occur while performing epidural anesthesia or analgesia for various indications, including postoperative and labour pain relief(4).

Leakage of cerebrospinal fluid through dural punctures appears to be the main cause of PDPH. Leakage of CSF through the dural hole causes decreased CSF Pressure and volume, which is followed by gravity dependent downward sagging of the brain resulting in traction on the pain sensitive structure around the brain(5).

In upright position, the pain is more as it exacerbate the traction on intracranial structures and increase trans dural lumbar CSF pressure leading to more loss. It is relieved when CSF volume and pressure return to normal. The headache which is throbbing and orthostatic is an important symptom of cerebral vasodilatation and intracranial congestion of blood and this supports the

hypothesis that the loss of CSF causes compensatory cerebral vasodilatation resulting in PDPH. (Monro Kellie Doctrine)(6).

Vandam and Dripps concluded from a large epidemiological study, that PDPH is significantly more common in young female and quickly ambulant patients, with the highest incidence occurring in obstetric patients(7). Classically PDPH is throbbing in nature, of varying severity, related to posture and present most commonly 48 hours of dural puncture. It may be accompanied by neck stiffness, nausea, vomiting and photophobia(7). Treatment includes simple oral analgesics, opioids, a high fluid intake, intravenous caffeine. Intermittent saline injections have been used in both prophylaxis and treatment of established PDPH; however, the most effective method of treatment of moderate to severe PDPH is an autologous epidural patch. Nearly 90% are relieved by the first autologous injection and further 8% by a subsequent injection(7). Long term follow up has confirmed its safety. If a second epidural patch is unsuccessful in relieving the headache, the patient should have a neurological assessment. Indication for neurological imaging are continues refractory headache, loss of its postural character, focal neurological signs and seizures not related to preeclampsia /eclampsia. MRI especially magnetic resonance angiography or venography has better discriminative value(5).

In 1956, with the introduction of 22G and 24G needles, the incidence was estimated to be 11 %(8). Today the use of fine gauge pencil point needles, such as the Whitacre and Sprotte has produced a greater reduction in the incidence of post dural puncture headache, which varies with the type of procedure and patients involved. It is related to the size and design of the spinal needle used, the experience of the personnel performing the dural puncture, and the age and sex of the patient(8). Anesthetists have been active in attempting to reduce the incidence of post spinal headache. Reducing the size of the spinal needle has made a significant impact on the incidence of post spinal headaches. This study will assess the magnitude of post dural puncture headache and associated factors after spinal anesthesia.

1.2 Literature Review

Prevalence of post dural puncture headache:

In the United States, there were 4 million births in 2012 and 61% of singleton vaginal births in 2008 received a spinal, epidural, or combined spinal –epidural procedure for labour analgesia. The overall prevalence of PDPH following spinal , epidural, or combined spinal-epidural anesthesia is approximately 1% with typical obstetric anesthesiology practices(9).

The overall prevalence of PDPH after intentional dural puncture varies from 0.1- 36%, the prevalence of dural puncture in obstetric practice in United Kingdom is 0.18% - 3.6%. Eighty percent of these patients suffer from PDPH(10).

In 2015, Babu et al carried out study in India, evaluation of post dural puncture headache using various sizes of spinal needles. They concluded that the prevalence of PDPH was found to be minimum with 26 gauge Quincke needle(11).

In 2013, Adugna Aregawa et al carried out study in which 166 patients undergone spinal anesthesia, 45(38.8%) patients developed PDPH. They concluded that the prevalence of post dural puncture headache was found to be high among patients in the university of Gondar teaching and referral hospital after spinal anesthesia in North West Ethiopia(12).

In 2010, E. Gisore et al carried out study in which they used quincke and pencil point needle. they found and concluded that the overall cumulative prevalence of PDPH was 20.35% but was significantly higher in patients in whom the quincke type of needle was used than in those spinal anesthetics were administered using the pencil point needle. They recommend that the quincke needles should not be used in the obstetric population(13).

Factors associated with PDPH:

In 1980, Gordon H, et al, in Southern Ontario found that the rate of PDPH after lumbar puncture can be minimized through strict attention to technique and the employment of a 25 gauge needle with the bevel parallel to the dural fibers(14).

In 2006, Christopher L et al, in John Hopkins Hospital Maryland conducted study on 2163 males and 1917 females to detect the effect of gender on incidence of post dural puncture

headache. They found that non pregnant female subjects had significantly higher odds of developing PDPH than male subjects(15).

In 2016, Monserrate et al, In Melbourne, Australia conducted study 338 patients to assess factors associated with the most common adverse event following lumbar puncture. They found and concluded that factors that acutely lower CSF pressure (sitting positioning or extracting very high volumes of CSF) may be associated with transient post lumbar puncture headache(16).

In 2013, Dagmar Oberhofer et al, at the University Hospital Sveti Duh in Zagreb, conducted study on 56 parturients undergoing cesarean section and 59 orthopedic patients undergoing arthroscopic knee surgery, who received standard spinal anesthesia using 23 gauge and 27 gauge Quincke spinal needles. All patients were less than 40 years of age. They found that both group had higher risk for development of PDPH and PDPH were significantly lower for male than non-pregnant female subject(17).

In 2016, chakraborty et al, In India conducted study on 300 patients who underwent different surgeries following spinal anesthesia performed either in sitting position or lateral position by 25 gauge Quincke needle. They found associated symptoms like neck stiffness, vomiting, with PDPH(18).

Onset time of post dural puncture headache:

In 2012, Kim et al, In Seoul, Korea conducted study on 70 patients who underwent recumbence for four hours after lumbar puncture. They found that the median onset time of PDPH was 16 hours (range 1-120 hours) after lumbar puncture. PDPH occurred within 1 day in 17 patients, within 2 days in 2 patients, within 3 days in 2 patients and 120 hours later in 1 day(19).

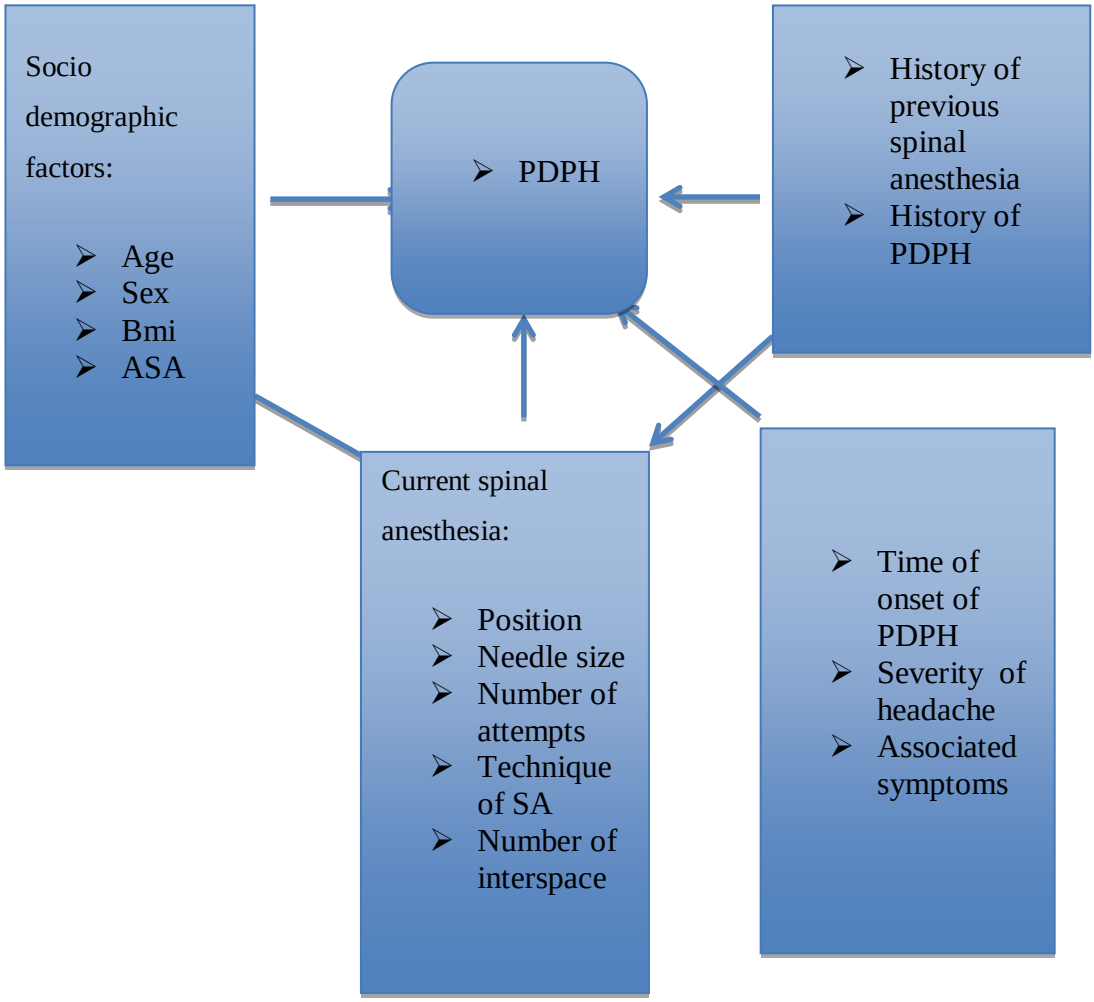
In 2014, Ravi Prakash et al, in King George's Medical University, Luck now, Uttar Pradesh India, Presented a case of successful use of epidural saline patch to treat PDPH caused by accidental dural puncture in a 45 years old female with large ovarian tumor. Patient developed headache 15 minutes post operatively(20).

In 2015, Rasooli et al, In Tabriz Iran conducted study on 319 ASA I and II physical status patients who underwent anesthesia for cesarean section, it was found that mild headache occurred in the first 24 hours, moderate in the first 48 hours. Severe headache was not observed(21).

In 2014, Baig T, In Pakistan conducted study on 60 patients to compare the frequency and severity of post dural puncture headache between 25 gauge cutting and non-cutting needles used for subarachnoid block in patients undergoing caesarean section, he found that patients developed headache on day 2 and 3 postoperatively. The frequency and severity of PDPH was higher in 25 gauge cutting spinal needle group as compared to non-cutting needle(22).

In Tanzanian perspective little has been done regarding local studies on prevalence of PDPH and associated factors in mothers for caesarean section. Currently there are no available literatures regarding prevalence of PDPH and associated factors in mothers for cesarean section in Tanzania.

1.3 Conceptual Framework



EXPLANATION OF THE CONCEPTUAL FRAME WORK:

The conceptual frame work diagram was designed by the investigator to show the factors which may influence the development of PDPH and the associated factors as it has been highlighted in the literature review (5,7, 14, 16, 19).

The researcher will meet the patient in two locations namely:

i. The admission ward where by the patient will be enroll in the study then patient socio-demographic factors will be recorded.

ii. In the operating theatre the techniques of spinal anesthesia induction will be documented and then the patient will be followed up the following day post operatively for assessment of PDH

iii. The socio-demographic factors such as younger age, female gender, young women with lower body mass index and those who are pregnant have the highest risk of developing post dural puncture headache. Factors contributing to the development of headache after lumber puncture are position, needle size, and number of attempts and the techniques of spinal anesthesia. These factors are modifiable; reducing the size of the spinal needle has made significant impact on the incidence of PDPH. Diagnosis mainly clinical, history of lumber puncture, previous history of PDPH, and the associated symptoms confirm the diagnosis.

1.4 Problem Statement

Post dural puncture headache is a common problem after spinal anaesthesia and a major psychological, physical, and economic burden for individual and the society. It is also one of the most frequent complaints and common reason for long hospital stay. Postdural puncture headache after spinal anaesthesia may result from a multitude of causes that include CSF leakage into the epidural space via a tear in the dura. The fall in intracranial pressure may also cause compensatory cerebrovascular vasodilatation and this may contribute to the development of the headache. Women, particularly during pregnancy and especially after vaginal delivery, are considered at increased risk for PDPH. The incidence of PDPH is highest between 18 and 40 years of age and declines in children younger than 13 years and adults older than 60 years. The incidence is greater in patients with lower body mass index. Younger women may be at a greater risk because of increased duralfiber elasticity that maintains a patent dural defect compared to a less elastic dura in older patients. Patients with a headache before lumbar puncture and a prior history of PDPH are also at increased risk. The incidence of post-dural puncture headache varies depending on the type and size of the needle used. A cutting needle would increase the rate compared to a pencil-point needle since it causes more damage to the fibers of the Dura. However no comprehensive data exist for the prevalence and incidence of PDPH in our setup, since PDPH do occurs and no definitive treatment regimen is in place to guide clinician; it is possible that there is significant inconsistency in the overall management of these cases in the hospital. Our country may not be an exception since PDPH has an impact on economy consideration both direct and indirect cost incurred due to the morbidity and length of hospital stay. This puts all of us as clinician, especially anesthetist at a very high state of alertness while we attend to them as our primary goal is patient’s safety. It is therefore pertinent that the above mentioned facts are studied.

1.5 Rationale

Spinal anesthesia is increasingly becoming the preferred anesthetic technique for elective caesarean section in MNH. However there is an evitable risk of PDPH after spinal anesthesia. PDPH may cause discomfort and this may result in increased rejection of regional anesthesia by patients. If the incidence of this complication is not minimized it has a potential to act as a drawback. Anesthetists have been active in attempting to reduce the incidence of post spinal headaches by reducing the size of spinal needle. Many factors influence the incidence of PDPH. These includes, size and design of spinal needle used, patient population, clinical setting, and criteria used to define PDPH and the experience of the operator. The actual prevalence of PDPH in elective C/S after spinal anesthesia at MNH is not known since no study has been done to address this issue. A common question remains .What is the prevalence of PDPH in elective C/S mothers after spinal anesthesia at MNH. The findings of this study will be used in suggesting means of further reducing the prevalence of PDPH. Improving the existing methods of management of PDP Hand lastly providing a window for future research on this subject. In addition, this research will be conducted as a partial fulfillment of my Master Degree Program in Anesthesiology.

1.6 Research Question

In our setting, what is the magnitude of post dural puncture headache and associated factors in elective cesarean section patients after spinal anesthesia?

1.7 Objectives

To assess the magnitude of post dural puncture headache and associated factors after spinal anesthesia at Muhimbili National Hospital.

1.7.1 Specific Objectives

1. To determine the prevalence of Post Dural puncture headache after spinal anesthesia among patients undergoing caesarean section at MNH between May and December 2016.
2. To determine factors associated with Post Dural puncture headache among patients undergoing caesarean section at MNH between May and December 2016.
3. To determine the onset time of post dural puncture headache among patients undergoing caesarean section at MNH between May and December 2016.

CHAPTER TWO

2.0 METHODOLOGY

2.1 Type of Study

A hospital based cross sectional study.

2.2 Study Area

This study was conducted at the maternity theatre and maternity wards at Muhimbili National Hospital in Dar Es Salaam, Tanzania. MNH is a teaching hospital and a referral center it is the largest in the country. It provides services to residents of Dar es Salaam and all other regions in Tanzania. The population of Dar Es Salaam was estimated to be more than 4 million people according to 2012 Tanzania population census. MNH has about 17 operating theatres. An average of 10000 elective surgeries is done annually. The hospital has maternity block which consists of five antenatal labour wards and two theatres that operates 24 hours.

2.3 Study duration

The study was conducted in about eight month period, beginning from May to December 2016

2.4 Study population

The study population included patients undergoing elective C/S under spinal anesthesia at MNH, during the duration of the study.

2.4.1 Inclusion Criteria

ASA I and II mothers scheduled for elective cesarean section

Signed consent form.

2.4.2 Exclusion Criteria

1. ASA > II
2. Emergency procedures.
3. Patients with impaired cognitive function.
4. Non consenting patients.
5. ASA I and II elective cesarean section mothers who had spinal anesthesia that:
    a) Had failed spinal anesthesia and general anesthesia was substituted.
    b) Developed complication other than PDPH during or / after surgery that required ICU admission.
    c) Mothers who had preexisting chronic headache.

2.5 Patients Involved

All patients who fulfilled the inclusion criteria and signed the consent form.

2.6 Sample Size Determination

The minimum sample size was calculated using the formula below

$$\mathbf{n=}\frac{\boldsymbol{Z^2 P\ (1-P)}}{\boldsymbol{D^2}}$$

Where:

n= required sample size

Z= Standard error of the mean corresponding to a 95% confidence interval.

(Standard value from a t –table 1.96)

P= Expected prevalence of PDPH = 20.35% estimated from previous study done in Aga Khan University, Nairobi 2010 by E. Gisore(13).

D = Target margin of error set at 5%.

Therefore from the formula above we substitute and calculate

$$\mathbf{n=}\frac{1.96^2 \times 0.07\ (1-0.2035)}{0.05^2}$$

Hence sample size will be 249

Considering 10% non-responses, by using this formula N= (n × 100%)/100%-f%
Where, n= adjusted minimum sample, and f % = non respondents
Then the sample size will be 276.

2.7 Procedures and Data Collection

Procedures and Data Collection

Preoperative

The approval to conduct the study was obtained from MNH/MUHAS ethics and research committee. Elective cesarean section mothers scheduled for spinal anesthesia were visited preoperatively, in their respective wards of admission, on the evening before the day of operation, by the principle investigator. The aims of the study were explained to the patient, then requested to sign informed consent. All mothers who consented were enrolled consecutively in the study. Data collection sheet for recording the information required was fixed in the patient's file after recruitment into the study.

Intraoperative

Inside the operation room, the principle investigator fills the data collection sheet. Patient's registration number, Age, Parity, Needle design, size, and number of attempted dural puncture and the time at which anesthesia was given were recorded.

Post-operative

Patients were visited by the principle investigator in their respective wards of admission after 24 hours, 48 hours and 72 hours postoperatively in order to record the presence or absence of headache, onset time of headache and other symptoms associated with the headache. A participant is diagnosed as having PDPH if she complains of occipital, frontal headache, exacerbated by sitting and standing, and alleviated by lying flat with associated symptoms such as neck stiffness, low back pain, nausea, vomiting, vertigo, tinnitus, and blurred vision.

2.8 Data Collection

The principle investigator and research assistants approached the clients individually after they have been admitted in the ward. A participant is questioned using a specially designed structured questionnaire after obtaining informed consent. The questionnaire was composed of three parts; each section was design to assess a specific component of the research.

Section one

This section involved the socio-demographic information (age, sex, parity, registration number).

Section two:

This contained maternity theater data (time at which spinal anesthesia is given, type and size of spinal needle and number of dural puncture attempts).

Section three:

This section contained questions useful for diagnosis of PDPH and follow up data in the maternity ward (time of onset of PDPH, type of needle and size and associated symptoms of PDPH such as neck stiffness, low back pain, nausea, vomiting, vertigo, tinnitus, and blurred vision).

Kiswahili language was used as the main medium of communication. Counseling conducted to the mothers for elective caesarean section under spinal anesthesia, explaining to them the purpose and aim of the study. A chance for point of clarification from clients was available. Client was free to ask questions whenever they feel so, and they can withdraw from the study as they wish and feel free not to answer questions that seems uncomfortable to them.

2.9 Data Analysis

Data entry, cleaning, coding and analysis was done using SPSS version 20.0. All variables were categorized and described using frequency distribution and bivariate analysis in computing association between risk factors and onset time was determined. The chi- square test was used to measure the strength of associations between variables, a p value of ≤ 0.05 was considered statistically significant. Results were presented in tables and graphs.

2.10 Ethical Clearance

The proposal was presented to the department of Anesthesiology of Muhimbili University of Health and Allied Sciences (MUHAS). Ethical clearance was there after obtained from the Senate Research and Publication committee of the Muhimbili University of Health and Allied Sciences.

2.11 Study Limitations

This study was subjected to some limitations. One of them being no standard tool for measuring BMI of the participants. Thus BMI was not included in the factors associated with high risk of development of PDPH in this study.

Also, only one type of spinal needle (Pencil point gauge 25) was used during the study period at MNH. Thus the study could not establish the effect of needle orientation in relation to the development of PDPH in the studied participants.

2.11Dissemination of Results

The findings from this study will be presented as dissertation (in partial fulfillment of Master Degree in anesthesiology of MUHAS), and in scientific seminars/conferences (abstract) and scientific report (manuscripts) will be prepared and submitted to MNH, Ministry of health for the purpose of sharing knowledge and improve on clinical management and reduction of prevalence of PDPH in the line of conduction of safe anesthesia and patient satisfaction. Also a manuscript will be submitted to relevant journals for research publication afterward. Another copy will be kept in the library archive.

CHAPTER THREE

3.0 RESULTS

A total of 276 women participated in the study. Their mean age was 29.3 yrs with SD of 5.7. More than half 141(51.1%) of the respondents were aged 20-29 years old, small proportion of the participants were aged less than 20 years with 3.3%. **(Table 1)**

Table 1: Distribution of participant's age group

Variable	Frequency	Percentages
Age group (years)		
Less than 20	9	3.3
20-29	141	51.1
30-39	109	39.5
Above 40	17	6.2

More than half (58.7%) of the participants were anaesthetized by nurse anesthetist, and about one third 85(30.8%) of the participant were anaesthetized by resident. Small proportions of the respondent were anaesthetized by specialist and registrar with 2.2% and 8.3% respectively. More than three quarter (87%) of the participants were anaesthetized by provider with experience of less than 5 years. Previous scar was an indication for most of the surgeries (caesarian sections) with 80.8%. More than half of the surgeries took 45 minutes and above. **(Table 2).**

Table 2: Distribution of anesthesia provider, anesthetic experience and indication for procedure

Variable	Frequency	Percentage
Anesthesia provider		
Specialist	6	2.2
Resident	85	30.8
Nurse Anaesthetist	162	58.7
Registrar	23	8.3
Anesthetist experience		
Less than 5 years	240	87
5 years and above	36	13
Indication of procedure		
Previous scar	223	80.8
Big baby	25	9
Breech presentation	11	4
CPD	11	4
Multiple pregnancy	6	2.2
Duration of procedure		
Less than 45 minutes	129	46.7
45 minutes and above	147	53.3

Most of the respondents 62.3%were infused with 1 to 2 liters of fluid (ringer lactate or normal saline) while the rest (37.7%) had 3 to 4 liters intravenous fluid. More than half 146(52.9%) of the respondents had perpendicular needle orientation. Number of respondents with single and multiple number of Dural puncture attempts were almost the same.**(Table 3)**

Table 3: Frequency distribution of quantity of intravenous fluid and number of dural puncture attempts

Variable	Frequency	Percentages
Intravenous fluid quantity		
1-2 liters	172	62.3
3-4 liters	104	37.7
Number of dural puncture attempts		
Single attempt	137	49.6
Multiple attempts	139	50.4

Slightly more than half 154(55.8%) of the respondents had PDPH, **(Figure1)**. Onset of PDPD was higher 24 hrs after surgery with 74(48%) followed by 48hrs and 72 hrs after surgery with 48(31.2%) and 32(20.8%) respectively. **(Figure2)**.

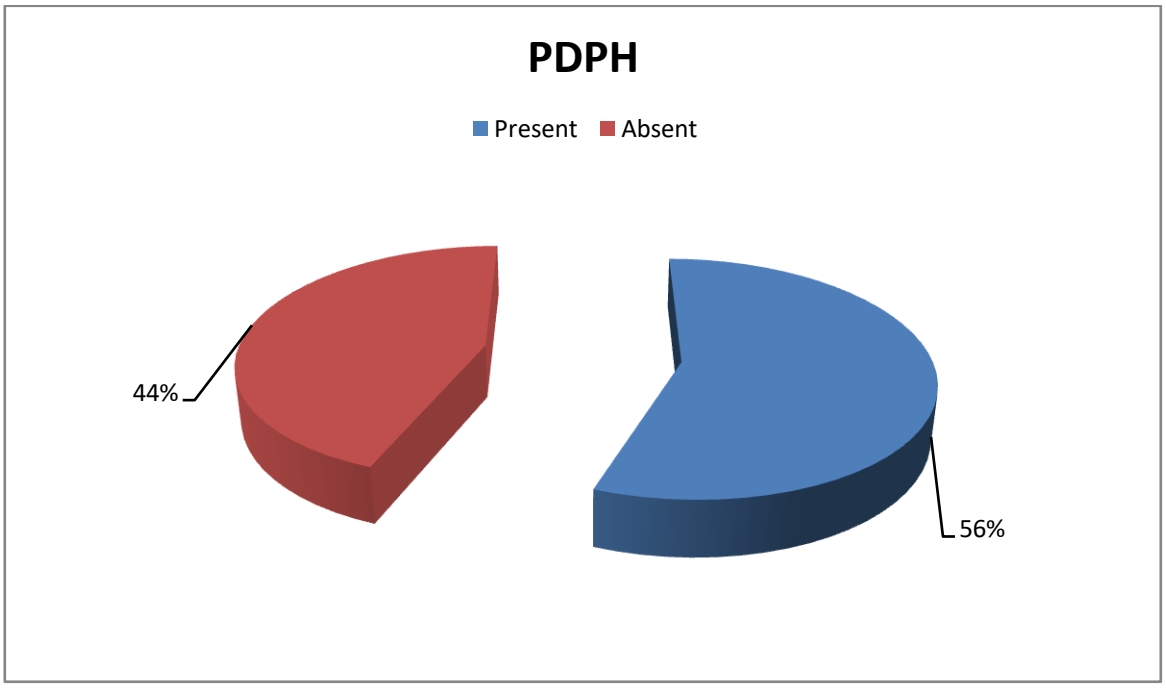


Figure 1: Distribution of PDPH among participants

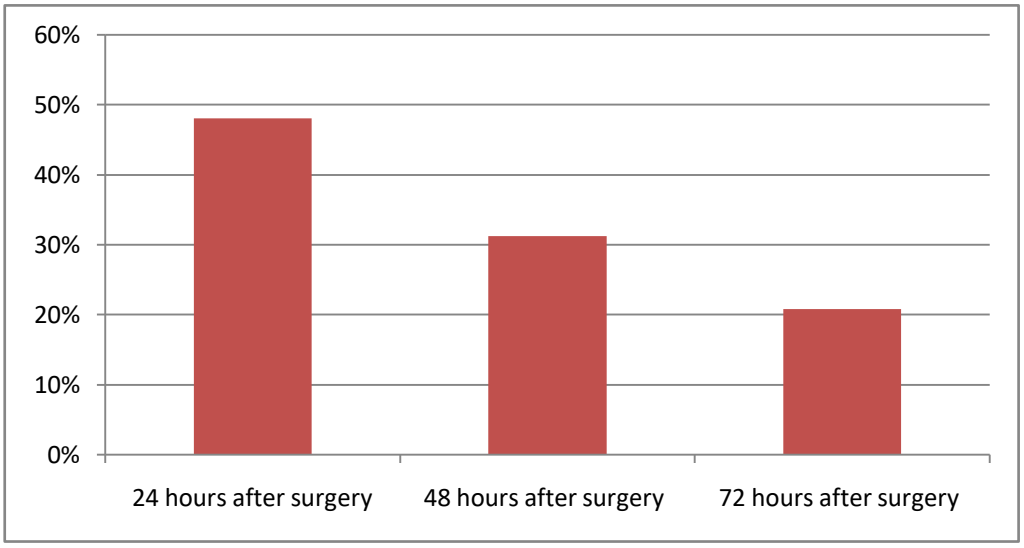


Figure 2: Percentage distribution of PDP Honest among participants

Factors associated with PDPH

Most of the participants who were anaesthetized by the specialist and registrar with 83.3% and 69.6% respectively didn't experience PDPH as compared to resident on which 80% had PDPH. PDPH was significantly associated with skill of the anesthesia provider (p value< **0.001**). Higher proportion 146(60.8%) of respondents anaesthetized by less experienced anesthetic provider develop PDPH. Less proportion 8(22.2%) of respondents anaesthetized by experienced provider had PDPH. There is strong association between PDPH and experience of anesthetic provider (p value<**0.001**).Higher proportion 133(95.7%) of respondents with PDPH were seen among those with multiple Dural puncture attempts.

Table 4: Distribution of PDPH with anesthesia provider, experience, number ofDural puncture attempts.

Variables	PDPH		Total	P value
	Present (n %)	Absent (%)		
Anesthesia provider				
Specialist	1(16.7)	5(83.3)	6	
Resident	68(80)	17(20)	85	≤ 0.001
Nurse Anaesthetist	78(48.1)	84(51.9)	162	
Registrar	7(30.4)	16(69.6)	23	
Anesthetist Experience				
less than 5 years	146(60.8)	94(39.2)	240	≤ 0.001
5 years and above	8(22.2)	28(77.8)		
Number of dural attempts				
Single attempt	21(15.3)	116(84.7)	137	≤ 0.001
Multiple	133(95.3)	6(4.3)	139	

Table 5: Distribution of PDPH with duration of surgery and IV fluid therapy

Variables	PDPH		Total	P value
	Present (n %)	Absent (n %)		
IV Fluids				
1 liter	9(56.2)	7(43.8)	16	
2 liters	89(57.1)	67(42.9)	156	≤ 0.878
3 liters	56(53.8)	48(46.2)	104	
Total	154(55.8)	122(44.2)	276(100%)	

Other Symptoms associated with PDPH

Less than half of the respondents had 124(45%) had other symptoms associated with PDPH. Higher numbers of the participants were having neck stiffness with 42(15.2%) followed by those with back pain 29(10.5%), 25(9.1%) for nausea, 19(6.5%) for vomiting, 4(1.4%) for vertigo, 2(0.7%) for tinnitus and 3(1.1%) for blurred vision **(Table 6)**

Table 6: Frequency distribution of symptoms associated with PDPH (n=276)

Symptoms	Frequency	Percentages
Neck stiffness	42	15.2
Low back pain	29	10.5
Nausea	25	9.1
Vomiting	18	6.5
Vertigo	4	1.4
Tinnitus	2	0.7
Blurred vision	3	1.1
No associated symptoms	31	11.2

CHAPTER FOUR

4.0 DISCUSSION

Prevalence

PDPH is a common complication for parturient undergoing neuraxial blockade and female sex, pregnancy and young age are purported to be associated with increased risk of developing PDPH following dura puncture(23).Different researches showed different values of the prevalence of PDPH. In this study the overall prevalence of PDPH was 56%. This result was found to be higher than the usual figures reported by most studies(24)(25). This is somehow comparable to the study done by Kassa AA et al. In their study they noted the prevalence of PDPH of 38.8% in a group of 124 patients undergoing procedure under spinal anesthesia in whom gauge 25 and gauge 20 were used to administered spinal anesthesia(12).The possible cause for the slight difference could be due to the use of 25gauge pencil point spinal needle to administer anesthesia in all cases in our study. The study participants were also prone to repeated number of attempts. The other possible cause could be the study participants were high risk patients for occurrence of PDPH younger age, female and pregnant mothers(25). In study done by Tafesse D et al in Black Lion Specialized referral hospital in patients undergoing orthopedic and urologic procedure under spinal anesthesia they noted the overall prevalence of PDPH was 33% in a group of 25 patients with quincke type 22G Spinal needles (26). They have small number of participants compared to our study.

Factors associated with onset of PDPH

The mean age of the study patients was 29.3 years. The mean age of the mothers who had developed headache was 26.84 years and for those who did not develop headache was 32.29 years, there was statistical significance in the occurrence of PDPH between mean age of the two group (p- value ≤ 0.001), this mean age group lies within 20-29 years of age group which is associated with the highest frequency of PDPH(26). These results are in accordance with the

study of Vallejo et al, in their study they noted a mean age of 32.1 years in the 172 patients in whom spinal anesthesia were performed using G 25 Quincke point Needles(27).The mean age group which was associated with onset of PDPH lies within 18-30 years in their study.

Only pencil point spinal needle gauge 25 was used to administer anesthesia in all the cases throughout the study period. The pencil type is the standard needle with a non cutting beveled, pencil point tip. In a prospective randomized double blind study of obstetrics patients undergoing elective cesarean section under spinal anesthesia by Manuel C.Vallejo et al in 2000,they noted that sprotte and whitacre pencil point needles and smaller diameter needles were associated with lower frequency of PDPH compared to cutting needles and large diameter needles Atraucan and Quincke respectively(27). This is in line with our study.

In this study 15.3% of patients had only one dural puncture attempt. The rest 95.7% had multiple dural punctures ranging from 2-6 times and they developed PDPH. Present findings are in congruence with that of Syed et al in their studies in a group of 75 patients, who had spinal anesthesia using 25G Quincke needle all patients who underwent subarachnoid block with multiple attempt had PDPH(28). In their study all the procedures were performed by the same anesthesiologist with enough experience, in our study different anesthesia providers performed the procedures and some of them with little experience. Muhimbili national hospital , being a teaching hospital ,some of the spinal anesthesia procedures were performed by registrars, nurse anesthetists and postgraduate anesthesia residents some of whom had little experience. This is reflected in the high frequency of dural puncture attempts noted in this study.

It has been shown that PDPH is more common if two verified punctures into the subarachnoid space made. Patients who had more than one attempt were likely to develop PDPH. This was statistically significant in this study (p-value ≤ 0.001).

In our study 56.2% of women who received 1 liter preloading developed PDPH and 57.1% of those who received 2 liters developed headache while 53.8% of those who received 3 liters developed PDPH. However this study was not able to demonstrate statistical significance in the relations between the type and volume of intravenous fluid therapy and the genesis of

PDPH among patient who developed PDPH and those who did not developed PDPH. P value ≤ 0.878

In similar study done by E. gisore et al in Agakhan University Hospital in Nairobi Kenya, in a group of 130 C/S mothers 12.5% of women who received more than 1500 milliliters of fluid developed PDPH. 19.5% of those who received between 1000 to 1499 mls of fluids developed PDPH and 27.2% of those women who received between half a liter of fluid and 999mls developed PDPH. Their study was not able to demonstrate statistical significance in the reduction in occurrence of PDPH between the patients who were pre loaded and those who were co loaded, p value ≤ 0.643(13).As such our study results compare very well with the Nairobi study.

Onset time of post dural puncture headache and associated symptoms

In our study, the onset of headache occurred in 48% of the patient in the first 24 hours, 31.2% of patients in the next 48hours and 20.8% in 72 hours after dural puncture. Ghosh et all in their study noted that the onset of headache after lumbar puncture is usually within 24 hours to 72 hours after dural puncture(29). This is consistent with our study.

Out of the 154 mothers who developed PDPH, 124 had a least other symptoms associated with PDPH. The frequency of symptoms were as follows, forty two (15.9%) for neck stiffness, twenty nine (10.5%) for low back pain, twenty five (9.1%) for nausea, nineteen (6.5%) for vomiting, four (1.4%) for vertigo, three (1.1%) for blurred vision and two (0.7%) for tinnitus. This is somehow comparable to the study done in Kenyata national hospital by Samuel M et al where they noted out of 58 mothers who developed PDPH,11 had at least one symptoms associated with PDPH and the frequencies of the symptoms are as follows; Six(10.3%) for neck stiffness, two (3.4%) for nausea, two(3.4%) for vertigo, one (1.7%) for low back pain, one (1.7%) for agitation and one (1.7%) for blurred vision respectively. This difference could be due to the large number of study population in our study compared to their small number 58 mothers.

Ahmed et al in the review on PDPH noted that the following symptoms were associated with PDPH, neck stiffness, low back pain, nausea, vomiting, vertigo and tinnitus and rarely diplopia due to cranial nerve palsy and even cortical blindness(30). This is consistent with our study.

CHAPTER FIVE

5.0 CONCLUSIONS AND RECOMMENDATIONS

5.1 Conclusion

The prevalence of PDPH in elective cesarean section mothers following spinal anesthesia in MNH maternity theatre was 56%. The mean age of elective cesarean section mothers who had spinal anesthesia in our study was 29.3, therefore young age group were more suspected to developed PDPH. Multiple dural puncture attempts during administration of anesthesia were associated with more risk of development of PDPH as compared to one dural puncture attempt. This was statistically significant p value < 0.001.Onset of PDPH among the patients who developed PDPH occurred in 74(48%) on the first day, 48(31.2%) on the second day and 32(20.8%) on the third day respectively.

This study was not able to demonstrate statistical significance in the reduction in PDPH between the volumes and types of fluid therapy p value ≤ 0.643.

Out of the 154 mothers who developed headache,124 had other symptoms associated with PDPH, twenty nine (10.5%) had low back pain, twenty nine (10.5%) had neck stiffness, twenty five (9.1%) had nausea, nineteen (6.5%) had vomiting, four (1.4%) had vertigo, and three (1.1%) had blurred vision.

5.2 Recommendations

Owing to the findings of the current study which reveal high risk of developing PDPH in participants who had multiple lumber puncture during spinal anaesthesia induction by Residents and nurse anaesthetists, it is therefore recommended that during training residents and nurse anaesthetists should avoid multiple dural puncture attempts.

A long term prospective study on the risk factors associated with severity of headache and duration of PDPH in C/S mothers undergoing spinal anesthesia in MNH should be considered. This may help the anesthetist to minimize the severity of PDPH and to be able to estimate the duration of follow up for those mothers that will have developed PDPH.

REFERENCES

1. Kuczkowski KM. Post-dural puncture headache in pregnant women : What have we learned? HISTORICAL PERSPECTIVE : Rev Colomb Anestesiol. 2006;34:267–72.

2. Wu C, Christo P. Postdural Puncture Headaches: An Overview . Int J Pain Med Pall …. 2004.

3. Ghaleb A. Post-dural puncture headache. 2012;(17):45–51.

4. Ghaleb A, Khorasani A, Mangar D. Post-dural puncture headache. Int J Gen Med. 2012;5:45–51.

5. Nath G, Subrahmanyam M. Headache in the parturient: Pathophysiology and management of post-dural puncture headache. J Obstet Anaesth Crit Care. 2011;1(2):57.

6. Nguyen D, Walters R. Standardizing Management of Post-Dural Puncture Headache in Obstetric Patients: A Literature Review. Open J Anesthesiol. 2014;(October):244–53.

7. Ahsan S, Kitchen N, Jenkins C. Incidence of Postdural Puncture Headache Following Spinal Anaesthesia for Lower Segment Caesarean Section with the 25 Gauge Polymedic Spinal Needle.

8. Turnbull DK, Shepherd DB. Post-dural puncture headache: Pathogenesis, prevention and treatment. Br J Anaesth. 2003;91(5):718–29.

9. Sachs A, Smiley R. Post-dural puncture headache: The worst common complication in obstetric anesthesia. Semin Perinatol. 2014;38(6):386–94.

10. Chohan U. Post dural puncture headache. 2016;(September 2003).

11. Babu DD, Chandar DD, Prakash CS, Balasubramanian S, Kumar KS. Evaluation of Post Dural Puncture Headache Using Various Sizes of Spinal Needles. 2015;3(9):9–13.

12. Kassa AA, Beyen TK, Denu ZA. Post Dural Puncture Headache (PDPH) and Associated Factors after Spinal Anesthesia among Patients in University of Gondar Referral and Teaching Hospital, Gondar, North West Ethiopia. J Anesth Clin Res. 2015;2015(7):1–6.

13. Gisore E, Mung'ayi V, Sharif T. Incidence of post dural puncture headache following caesarean section under spinal anaesthesia at the Aga Khan University Hospital, Nairobi. East Afr Med J. 2010;87(6):227–30.

14. Morewood GH. CURRENT REVIEW *' ACTUALITES A rational approach to the cause , prevention and treatment of postdural puncture headache. 1993;149(8):1087–93.

15. Courpas GE, Joe EM, Liu SS. Gender and Post – Dural Puncture Headache. 2016;(3):613–8.

16. Monserrate AE, Ryman DC, Ma S, Xiong C, Noble JM, Ringman JM, et al. HHS Public Access. 2016;72(3):325–32.

17. Oberhofer D, Klebar I. Incidence and clinical significance of post-dural puncture headache in young orthopaedic patients and parturients. 2013;115(2):203–8.

18. Chakraborty A, Sinha A. The incidence of Post Dural Puncture Headache Following Spinal Anaesthesia: - A Comparison of Sitting Versus Lateral Decubitus Position. 2016;3(7):2096–9.

19. Kim SR, Chae HS, Yoon MJ, Han JH, Cho KJ, Chung SJ. No effect of recumbency duration on the occurrence of post-lumbar puncture headache with a 22G cutting needle. 2012;2–6.

20. Prakash R, Gautam S, Jafa S. CA SE REP ORT Postdural puncture headache : Is epidural saline patch effective – A case report. 2014;5(4):100–2.

21. Rasooli S, Moslemi F, Baybordi A. Post-dural Puncture Headache in the Obstetric Patien: Needle Size , Number of Dural Puncture and Timing of Ambulation. 2015;1–5.

22. Baig T. Anesthesia & Clinical Comparison of 25 Gauge Cutting with Noncutting Needles for Post Dural Puncture Headache in Obstetric Patients. 2014;5(10):10–2.

23. Evans RW, Armon C, Frohman EM, Goodin DS. ASSESSMENT : PREVENTION OF POST – LUMBAR PUNCTURE HEADACHES Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology. 2000;55:909–14.

24. Douglas MJ, Ward ME, Campbell DC, Bright SB, Merrick PM. Factors involved in the incidence of post-dural puncture headachewith the 25 gaugeWhitacre needlefor obstetric anesthesi. Int J Obs Anesth. 1997;6(I 997):220–3.

25. Amorim JA, Gomes de Barros M V, Valença MM. Post-dural (post-lumbar) puncture headache: Risk factors and clinical features. Cephalalgia. 2012;32(12):916–23.

26. McSwiney M, Phillips J. Post dural puncture headache. Acta Anaesthesiol Scand [Internet]. 1995;39(7):990–5.

27. Vallejo MC, Mandell GL, Sabo DP, Ramanathan S. Postdural puncture headache: a randomized comparison of five spinal needles in obstetric patients. Anesth Analg. 2000;91(4):916–20.

28. Syed S, Qayoom N, Naaz S, Mushtaq K, Mir AH, Bijli AH, et al. Comparison of post-dural puncture headache- incidence and severity in obstetric patients after spinal anesthesia for caesarean section with 25G and 27G quincke needle. 2017;5(2):596–600.

29. Ghosh S, Nayak S, Roy S. Assessment of Post Dural Puncture Headache in Patients Undergoing Caesarean Section: A Comparison between 25 G Quinke V/S Whitacre Needles. Br J Med Med Res. 2017;19(9):1–7.

30. Ahmed S V, Jayawarna C, Jude E. Post lumbar puncture headache: diagnosis and management. Postgrad Med J. 2006;82(973):713–6

31. Samuel M. Incidence of Post Dural puncture headache in elective cesarean section patients following spinal ane*sthesia at Kenyatta National Hospital. 2009;(May).*

APPENDICES

Appendix 1: Criteria of post dural puncture headache diagnosis:

1. Occurred after mobilization.
2. Aggravated by erect or sitting position and coughing, sneezing or straining.
3. Relived by lying flat.
4. Mostly localized in occipital, frontal or generalized.

Appendix 2: Table (1) headache severity.

Mild	No limitation of activity. No treatment required.
Moderate	Limited activity, regular analgesic required.
Severe	Confined to bed, anorexic, unable to feed the baby.

Appendix 3: American Society of Anaesthesiologist (ASA) Physical Status Classification.

ASA I: A normal healthy patient.

Example: 20 years old healthy female nonsmoking, no or minimal alcohol use.

ASAII: A patient with mild systemic disease.

Example: Mild diseases only without substantive functional limitations. Examples included (but not limited to) current smoker, social alcohol drink, pregnancy, obesity, well controlled DM/HTN, mild lung disease.

ASA III: A patient with severe systemic diseases.

Example : Substantive functional limitations, one or moderate to severe diseases example include (but not limited to) poorly controlled DM, or HTN, COPD, morbid obesity BMI ≥40, active hepatitis , alcohol dependence or abuse, implanted pace maker, moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis, premature infant, history of recent MI,CVA,TIA, or CAD/stents.

ASA IV: A patient with severe systemic disease that is a constant threat to life.

Examples include (but not limited) to recent MI, CVA, or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction to ejection fraction, sepsis, DIC, ARD, or ESRD not undergoing regularly scheduled dialysis.

ASA V: A moribund patient who is not expected to survive without the operation.

Examples include but not limited to ruptured abdominal /thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ /systemic dysfunction.

ASAVI: A declared brain dead patient whose organs are being removed for donor purposes.

The addition of ‘’E’’ denotes Emergency surgery. An emergency is defined as existing when delay in treatment of the patient would lead to significant increase in the threat to life or body part.

Appendix 4: Quality of evidence ratings for therapeutic modalities.

Class I: Evidence proved by one or more well designed randomized control clinical trials.

Class II. Evidence provided by one or more well designed clinical studies, such as case control, cohort studies, etc.

Class III: Evidence provided by expert opinion, non-randomized historical controls or reports of one or more.

Appendix 5: Data sheet form (Questionnaire) Adopted from Samuel M et al, 2009(31)**.**

Section one:

- ✓ **Sociodemographic Data**

a) Serial number ……

b) Registration number

c) Date ……..

d) Contact/ mobile number.

e) Age…….

f) Sex ……

g) Parity……..

Section two:

- ✓ **Maternity Theatre Data**
- ✓ **Spinal needle used**

a) Type…….. b) Size……..

- ✓ **Anesthesia Provider**

a) Specialist …….

b) Resident ……..

c) Nurse Anaesthetist ……..

d) Registrar……..

- ✓ Experience of the anesthetic provider in years……..
- ✓ Indication of procedure…….
- ✓ Duration of procedure……
- ✓ Intravenous fluids given in liters intraoperatiely……..
- ✓ **Type**

a) Ringer lactate……

b) Normal Saline…….

- ✓ **Number of dural puncture attempts……**

- ✓ **Section three:**

- ✓ **Follow Up Data In Maternity Wards.** (Thick where appropriate)

  PDPHis

  a) Present …….(occipital, frontal, generalized headache. aggravated by erect or sitting position , coughing , straining, or sneezing and relieved by lying flat)

  b) Absent……

- ✓ **Time of onset of PDPH after spinal block. (**Thick where appropriate)

  a) 24hrs……..

  b) 48hrs……

  c) 72hrs……

- ✓ **Other symptoms associated with post dural puncture headache:**

  a) Neck stiffness…….

  b) Low back pain……..

  c) Nausea……

  d) Vomiting ……

  e) Vertigo ……..

  f) Tinnitus…….

  g) Blurredvision……

Appendix 6: Consent Form - English Version

CONSENT TO PARTICIPATE IN THE STUDY, PREVALENCE OF POST DURAL PUNCTURE HEADACHE AND ASSOCIATED FACTORS IN MOTHERS FOR ELECTIVE CESAREAN SECTION AT MUHIMBILI NATIONAL HOSPITAL

Dear Sir/Madam,

Greetings, My name are Dr. Hakim Stephen Cizario Odu, a resident doctor in the Department of anesthesia at MUHAS. I am conducting a study regarding the incidence of post dural puncture headache in elective cesarean section patients following spinal anesthesia at MNH.

I am requesting your participation.

Purpose of the study:

The aim of this study is to assess the incidence of post dural puncture headache in elective cesarean section patients following spinal anesthesia at MNH

How to participate:

Patients who will be ready to participate will sign this consent form to approve her willingness.

Short interview will be done and Patient's Registration Number, Age, Parity, needle design, size, and orientation and number of attempted dural punctures and time at which anesthesia is given will be recorded. Postoperatively patients will be visited by the principle investigator daily in their respective wards of admission everyday till they are discharge from hospital in order to record the incidence, onset time and severity of PDPH and other symptoms associated with PDPH.

Confidentiality:

Information obtained from you will be confidential and will be of help in this study and better care for this group of patients in future.

Costs:

You will not be required to pay anything for your participation.

Voluntary participation and rights to withdraw:

Your participation is voluntary and you have the right to withdraw from participating in our study at any time before the procedure. Whatever your decision may be, it will not affect in any way, your rights to care and treatment.

Risks:

We do not expect any risk the study is observational.

Benefits:

Your participation in this study will help you know about PDPH due to spinal anesthesia.
You will as well get the benefit of getting appropriate treatment as per need.
We hope that the information from this research will be useful in contributing to improve the quality of care in daily procedures and develop appropriate protocol.

Contact persons:

If you have any inquiries about this study, please do not hesitate to contact:
Dr. Hakim Stephen
Principal Investigator
Muhimbili University of Health and Allied Sciences (MUHAS)
Department of Anesthesiology
P.O. Box 65001 Dar Es Salaam.
Tel. +255 689596834.
OR in case of any information about your rights as a participant in this study please contact:
Professor Said Aboud
Chairperson
Senate Research and Publication Committee

Muhimbili University of Health and Allied Sciences (MUHAS)

P.O. Box 65001 Dar es Salaam

Tel. 2151489

I will be grateful if you would agree to participate in this study.

I _____

Have understood the above information and my questions have been answered by the investigator to my satisfaction. I willingly agree to take part in this research.

Name of the participant: _____

Signature of the participant: _____Date _____

Signature of Investigator _____ Date: _____

Appendix 7: Consent Form - Swahili Version

FOMU YA MAKUBALIANO YA KUSHIRIKI KATIKA UTAFITI

Habari! Mimi ni Dk.Hakim Stephen Cizario Odu, ni Daktari ninayesomea shahada ya Uzamili wa udaktari bingwa wa nusu kaputi katika Chuo Kikuu Cha Sayansi na Tiba za binadamu Muhimbili. Nafanya utafiti kuhusu maumivu ya kichwa yanayoletwa baada ya kuchomwa sindano ya usingizi mgongoni.

Ninaomba ushirikiano wako.

NiayaUtafiti

Dhumuni ni kujua kwakiwango gani wagonjwa wasio wa dharura, wanaochomwa sindano ya dawa ya usingizi mgongoni wanapata maumivu ya kichwa.

Jinsi ya Kushiriki:

Wagonjwa ambao wako tayari kushiriki wataweka sahihi zao,ili kuonyesha utayari.Yatafuata maswali mafupi ya Utangulizi, kasha aina za sindano na mara ngapi mgonjwa amechomwa sindano,muda ambao mgonjwa alichomwa sindano vita rekodiwa.Baada ya upasuaji wa Mgonjwa na wataonwa na mtafiti mkuu kila siku katika wodi za ona kuangalia muda gani maumivu yalianza na kwa kiasi gani na dalili nyinginezo zinazooana na maumivu yanayosababishwa na sindano ya usingizi mgongoni vita rekodiwa mpaka wagonjwa watakaporuhusiwa wodini.Wagonjwa watapigiwa simu kutoka kwa mtafiti mkuu siku ya kumi na nne baada ya kufanyiwa upasuaji ili kuweza kuangalia maumivu ya kichwa yaliyochelewa.

Usiri:

Taarifa ya matokeo hazitatangazwa kwa yoyote zaidi ya mtafiti.Matokeo ya utafiti kwa ujumla yatasaidia kuboresha huduma ya tiba kwa wagonjwa kama hawa kwa siku zijazo.

Gharama:

Hutatakiwa kulipa gharama yoyote kwa kushiriki kwako.

Utayari wa kushiriki au kujitoa:

Kushiri kikwako ni hiyari na waweza kujitoa.Lakini haitakunyima haki ya kupata tiba zingine.

Hatari:

Hatutaraji ihatari kutokana yoyote kutoka kwa utafiti huu.

Faida:

Kushiriki kwako katika utafiti huu kutakusaidia kujua maumivu ya kichwa yanayosababishwa na kuchomwa sindano ya usingizi mgongoni.

Pia utafaidika kupata matibabu halisia kama itakavyokuwa inahitajika.

Nitakushukuru kwa kushiriki kwako utafiti huu.Ahsante.

Iwapo utakuwa na swali lolote kuhusu utafiti huu wasiliana na

Dr. Hakim Stephen Cizario Odu, Chuo Kikuu Cha Afya na Sayansi za Tiba Muhimbili; IdarayaTiba; S.L.P 65001

Dar es Salaam. Simu+255 689596834.

AU

Endapo utakuwa na swali lolote kuhusu haki zako kama mshiriki katika utafiti huu wasiliana na:

Prof.Said Aboud; Mkurugenzi wa kamati ya utafiti na matoleo chuoni. Chuo Kikuu Cha Afya na Sayansi za Tiba Muhimbili; S.L.P 65001 Dar es Salaam; Simu 2151489.

Mimi……nimeelezwa/nimesoma yaliyomo katika fomu hii na nimeelewa maana yake. Nakubali kushiriki katika utafiti huu.

Sahihi…….. (Mshiriki) Tarehe……..

Sahihi…….. (Mtafiti) Tarehe……..