

**BED REST VERSUS EARLY MOBILIZATION IN PREVENTING  
POST-DURAL PUNCTURE HEADACHE IN SPINAL ANAESTHESIA**

**A RANDOMIZED CONTROLLED STUDY**

**BY**

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## **CONTENTS**

|                                    |      |
|------------------------------------|------|
| <b>DEDICATION</b> .....            | v    |
| <b>LIST OF ABBREVIATIONS</b> ..... | vii  |
| <b>OPERATION DEFINITIONS</b> ..... | viii |
| <b>ABSTRACT</b> .....              | x    |
| <b>CHAPTER ONE</b> .....           | 1    |
| 1.0 INTRODUCTION.....              | 1    |
| 1.1BACKGROUND .....                | 1    |
| 1.2 PROBLEM STATEMENT.....         | 2    |
| 1.3 JUSTIFICATION .....            | 4    |
| 1.4 RESEARCH QUESTION .....        | 4    |
| 1.5 OBJECTIVES OF THE STUDY .....  | 4    |
| 1.51 GENERAL OBJECTIVE .....       | 4    |
| 1.52 SPECIFIC OBJECTIVE .....      | 4    |
| 1.6 HYPOTHESIS .....               | 4    |
| 1.7 CONCEPTUAL FRAMEWORK.....      | 5    |
| <b>CHAPTER TWO</b> .....           | 6    |
| 2.0 LITERATURE REVIEW .....        | 6    |
| 2.1 Historical Background .....    | 6    |
| 2.2 Factors influencing PDPH ..... | 11   |
| 2.3 Applied anatomy .....          | 14   |
| 2.4 Applied physiology .....       | 16   |
| 2.5 Treatment of PDPH .....        | 18   |
| <b>CHAPTER THREE</b> .....         | 20   |
| 3.0 RESEARCH METHODOLOGY .....     | 20   |
| 3.1 STUDY DESIGN.....              | 20   |

|   |    |
|---|----|
| 3.2 STUDY SETTING .....   | 20 |
| 3.3 POPULATION .....  | 20 |
| 3.31 Target population .....  | 20 |
| 3.32 Accessible population .....  | 20 |
| 3.33 Study population .....   | 21 |
| 3.4 SELECTION CRITERIA .....  | 21 |
| 3.41 Inclusion .....  | 21 |
| 3.42 Exclusion. ....  | 21 |
| 3.5 RANDOMIZATION.....  | 22 |
| 3.51 Sequence Generation.....   | 22 |
| 3.52 Allocation .....   | 22 |
| 3.53 Implementation .....   | 22 |
| 3.6 SAMPLE SIZE.....  | 23 |
| 3.7 Sampling method .....   | 24 |
| 3.8 PROCEDURE .....   | 24 |
| 3.9 STUDY VARIABLES .....   | 26 |
| 3.91 DATA MANAGEMENT.....   | 26 |
| 3.92 DATA ANALYSIS .....  | 27 |
| 3.93 ASSESSMENT OF ACCURACY OF RANDOMIZATION .....                              | 27 |
| 3.94 BASELINE DEMOGRAPHICS AND CLINICAL CHARACTERISTICS OF THE TWO GROUPS ..... | 27 |
| 3.95 STOPPING RULES.....  | 28 |
| 3.96 QUALITY ASSURANCE.....   | 28 |
| 3.97 DISSEMINATION OF RESULTS.....  | 28 |
| 3.98 ETHICAL CONSIDERATIONS .....   | 29 |
| CHAPTER FOUR: .....   | 30 |
| DISPLAY AND INTERPRETATION OF RESULTS.....                                      | 30 |
| 4.1 DESCRIPTION OF THE STUDY POPULATION .....                                   | 31 |

|  |    |
|--|----|
| 4.2 COMPARING THE CHARACTERISTICS OF THE TWO GROUPS .....              | 33 |
| 4.3 OCCURRENCE OF HEADACHE FOLLOWING SPINAL ANAESTHESIA .....          | 34 |
| 4.4 ASSOCIATION OF POSTDURAL PUNCTURE HEADACHE IN THE TWO GROUPS ..... | 36 |
| CHAPTER FIVE: .....  | 38 |
| DISCUSSION.....  | 38 |
| 5.1 DEMOGRAPHIC CHARACTERISTICS .....                                  | 38 |
| 5.2 CONCLUSIONS.....   | 42 |
| 5.3 RECOMMENDATIONS.....   | 42 |
| REFERENCES .....   | 43 |
| Appendix 1: QUESTIONNAIRE .....  | 49 |

## **DEDICATION**

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The invaluable work done by Dr Nicholas Kisa, in analyzing the data, cannot be over emphasized.

## **LIST OF ABBREVIATIONS**

|             |  |
|-------------|--|
| <b>LP</b>   | Lumbar puncture                        |
| <b>CSF</b>  | Cerebrospinal fluid                    |
| <b>PDPH</b> | Postdural puncture headache            |
| <b>MRI</b>  | Magnetic resonance imaging             |
| <b>BMI</b>  | Body mass index                        |
| <b>EBP</b>  | Epidural blood patch                   |
| <b>RNG</b>  | Random number generation               |
| <b>ASA</b>  | American society of anesthesiologists. |

## **OPERATION DEFINITIONS**

**Postdural puncture headache;**- A postdural puncture headache (PDPH) or "spinal headache" is usually described as a severe, dull, non-throbbing pain, usually fronto-occipital, which is aggravated in the upright position and diminished in the supine position. It may or may not be accompanied by nausea, vomiting, visual disturbances and/or auditory disturbances.

**Bed rest;**- Lying in supine position for or greater than 12 hours in a day.

**Early mobilization;**- Any positions or posture a patient may assume after spinal anaesthesia apart from supine position.

**Spinal anaesthesia;**- It is a type of regional anaesthesia where the anaesthetic agent is directly administered in the subdural space.



## **LIST OF TABLES AND FIGURES**

|   |    |
|---|----|
| TABLE 1 Description of the study population.....                                | 31 |
| TABLE 2 Classification and types of operation among the study participants..... | 32 |
| TABLE 3 Comparing characteristics of the two groups.....                        | 33 |
| TABLE 4 Occurrence of headache in the different group.....                      | 34 |
| TABLE 5 Association of postdural headache in the two groups.....                | 36 |
| FIGURE 1: Conceptual framework.....   | 5  |
| FIGURE 2: Occurrence of post spinal headache.....                               | 35 |

## ABSTRACT

**Background:** Postdural Puncture Headache (PDPH) is a rare occurrence in spinal anaesthesia. Many studies have been done about the possible causes and CSF leakage has been identified as the cause of this headache. Bed rest has been used to control this headache once it occurs but not known whether it could also prevent it. Early mobilization in this study was defined as any posture a patient can resume other than keeping in supine position.

**Objectives:** To establish whether early mobilization increases chances of developing PDPH in Nsambya hospital.

**Methodology:** This was an open randomized controlled trial. A total of 110 patients were enrolled and randomized in each study arm. Questionnaires were used, and informed consent obtained. Spinal anesthesia was given using a 25 gauge needle. Participants were assessed for PDPH at 6, 12, 24, 48hours and a follow up at one week. Data was analyzed using SPSS study variables were HIV status, BMI, age, gender, number of needle attempts and type of operation Significance level was set at  $P < 0.05$ ).

**Results:** Seventy eight (79.1%) females, the majority of participants were overweight 98(89%). Emergency operations were 62(56.4%) while elective operations (48)43.6%. Laparotomy 14(11.8%), caesarian sections were 72(65.5%), perineum and groin operations were 14(12.7%), trauma and orthopedic were 9(8.2%) and other operations were 2(1.8%). HIV sero positive participants were 15(13.6%) seronegative participants were 93 (84.5%). 12 patients developed PDPH 4(3.6%) from the early mobilization group and 8(7.2%) from the bed rest group though there was no statistical significance  $P = 0.136$

**Conclusion:** There are no benefits in keeping post spinal patients on bed rest though if PDPH develops lying flat reduces this headache. All those participants who developed the headache were able to improve on paracetamol without other aggressive management like epidural blood patch.

## CHAPTER ONE

### 1.0 INTRODUCTION

#### 1.1 BACKGROUND

It has been just over one hundred years since Dr. Bier experienced and wrote about the first reported postdural puncture headache. Dr. Bier's classic description of his severe postdural headache would be familiar to anyone in practice today. A postdural puncture headache (PDPH) or "spinal headache" is usually described as a severe, dull, non throbbing pain, usually fronto-occipital, which is aggravated in the upright position and diminished in the supine position. It may or may not be accompanied by nausea, vomiting, visual disturbances and/or auditory disturbances. Patients who experience a postdural puncture headache should not be taken lightly. Data obtained from the ASA's closed claims analysis project show that this is the third most common reason for litigation in obstetric anesthesia<sup>[1]</sup>. Anyone being treated for a PDPH should receive reassurance as well as a full and frank discussion of treatment options.

Several theories have identified the leakage of cerebrospinal fluid (CSF) through the hole in the dura as a cause of this side effect. Therefore, it is necessary to take preventive measures to avoid this complication.

Post-dural puncture headache (PDPH) is an iatrogenic complication of spinal anesthesia. Causes reported to influence the incidence of PDPH are sex, age, pregnancy, previous history of PDPH<sup>1</sup>, needle tip shape<sup>2,3</sup>, needle size<sup>1,2</sup>, bevel orientation<sup>1,4</sup>, number of lumbar puncture (LP) attempts<sup>1</sup>, median versus paramedian approach<sup>5</sup>, type of local anesthetic solution<sup>6</sup>, and clinical  
Although the loss of cerebrospinal fluid (CSF) and lowering of CSF pressure is not a controversial subject, the actual mechanism producing the headache is unclear. There are two possible explanations. First, the decrease in CSF pressure may cause traction on the pain-sensitive intracranial structures in the upright position, leading to the characteristic headache. Secondly, the loss of CSF may produce a compensatory vasodilatation<sup>8</sup>. The incidence of PDPH was 66% in 1898<sup>9</sup>, which was likely due to the use of large gauge, medium bevel, cutting spinal needles. In 1956, with the introduction of 22-gauge and 24-gauge needles, the incidence was estimated to be 11%<sup>10</sup>.

Today, the use of needles such as the Sprotte and Whitacre has further reduced the incidence of PDPH, which varies with the type of procedure and patients involved. PDPH is significantly more common in young females, with the highest incidence occurring in obstetric patients<sup>10</sup>. There are two common techniques used in spinal anesthesia, median and paramedian, each of which has advantages and disadvantages. The median approach is the most common technique used, but it is technically difficult, especially in geriatric patients, because they have degenerative changes in the structural components of their spine. The paramedian approach is sometimes preferred because of faster catheter insertion<sup>11</sup>, fewer attempts at needle insertion<sup>12</sup>, and possibility of performing the procedure in an unflexed spinal position<sup>13</sup>; furthermore, identification of the epidural space may be easier with the paramedian technique. This technique is also less affected by osteoarthritic changes in the elderly population; however, the oblique direction is likely to cause problems when inserting the catheter-over-needle system through the epidural needle.

A paramedian approach is believed to decrease the risk of PDPH, but this has not been verified in clinical trials<sup>5</sup>.

Prolonged bed rest has been used as a therapeutic measure once PDPH has started, but it is unknown if it can also be used to prevent it. Similarly, the value of administering fluids additional to those of normal dietary intake to restore the loss of CSF produced by the puncture is unknown. A PDPH is usually a self-limiting process. If left untreated, 75% of them will resolve within the first week and 88% will have resolved by 6 weeks<sup>[2]</sup>.

Most treatments are geared towards lessening the pain and symptoms until the hole in the Dura can heal, or at least until it can close to the point where the symptoms are tolerable. So-called "conservative treatment" involves hydration, bed rest and analgesics.

## **1.2 PROBLEM STATEMENT**

Currently the practice in Nsambya hospital for the prevention of post-Dural puncture headache is by emphasizing to the postoperative patients to keep in supine position for more than 12 hours postoperatively. The practical application of such an intervention has not been proved to be beneficial in addressing the problem.

Restricting postoperative patients from early mobilization as in change of posture causes a considerable discomfort and has been implicated in the development of deep vein thrombosis.

Over the past one century, the incidence of PDPH has sharply decreased from ~70% to ~1%<sup>5</sup>, whereas the recently reported occurrence of PDPH is still seeing a big difference in various clinical settings from different regions when diverse techniques were used in patients with different ages. The incidence of PDPH in Obstetrics in Middle East is 2-4.6%<sup>12</sup>, 22.7% in Western Africa<sup>19</sup>, 16.9% in Southeast Asia, 16.6% in North Europe, and 6% in North America<sup>20</sup>.

According to the International Headache Society, the criteria for a low CSF pressure PDPH, include a headache that develops less than 7 days after a spinal puncture, occurs or worsens less than 15 minutes after assuming the upright position and improves after less than 30 minutes in the recumbent position. The headache should disappear within 14 days after a spinal puncture; if it persists it is called a CSF fistula headache

The classic explanation for the pathophysiology of a PDPH was thought that CSF leaking from a Dura puncture would lead to a loss of CSF pressure in the spine and a loss of buoyancy supporting the brain. When the patient assumes an upright posture, the brain sags, and tension on the meninges and other intracranial structures creates the pain seen with PDPH. As Sechzer pointed out in the 1970s, this explanation is probably overly simplified<sup>[3]</sup>.

It is likely that as the body assumes a vertical posture, the hydrostatic gradient across the brain increases, forcing more CSF to exit the dural puncture. The body then attempts to compensate for the loss of intracranial volume by vasodilatation. Much of the pain in a PDPH would then be related to vascular distention. This process would reverse itself when the patient again became supine.

This difference in mechanisms is an important one. If some or all of the pain of a PDPH is the result of processes similar to those that occur during a vascular headache, then a PDPH should be susceptible to the treatments used for vascular type headaches. In fact, these treatments have met with varying degrees of success.

### **1.3 JUSTIFICATION**

Taking in consideration the discomfort of keeping the postoperative patients in the supine position for long with the morbidity implications, there was a need to scientifically prove the benefits of such practice. Secondly in order to offer the most optimal prevention of PDPH we decided to investigate the outcomes of bed rest versus early mobilization.

The purpose of this study was therefore to establish if there are any benefits in restriction of movements for the prevention of PDPH.

### **1.4 RESEARCH QUESTION**

Among patients who are given spinal anaesthesia in Nsambya hospital , does bed rest offer better prevention of Post Dural Puncture headache than early mobilization?

### **1.5 OBJECTIVES OF THE STUDY**

#### **1.51 GENERAL OBJECTIVE**

To compare the outcome of early mobilization versus bed rest in the prevention of PDPH following spinal anaesthesia.

#### **1.52 SPECIFIC OBJECTIVE**

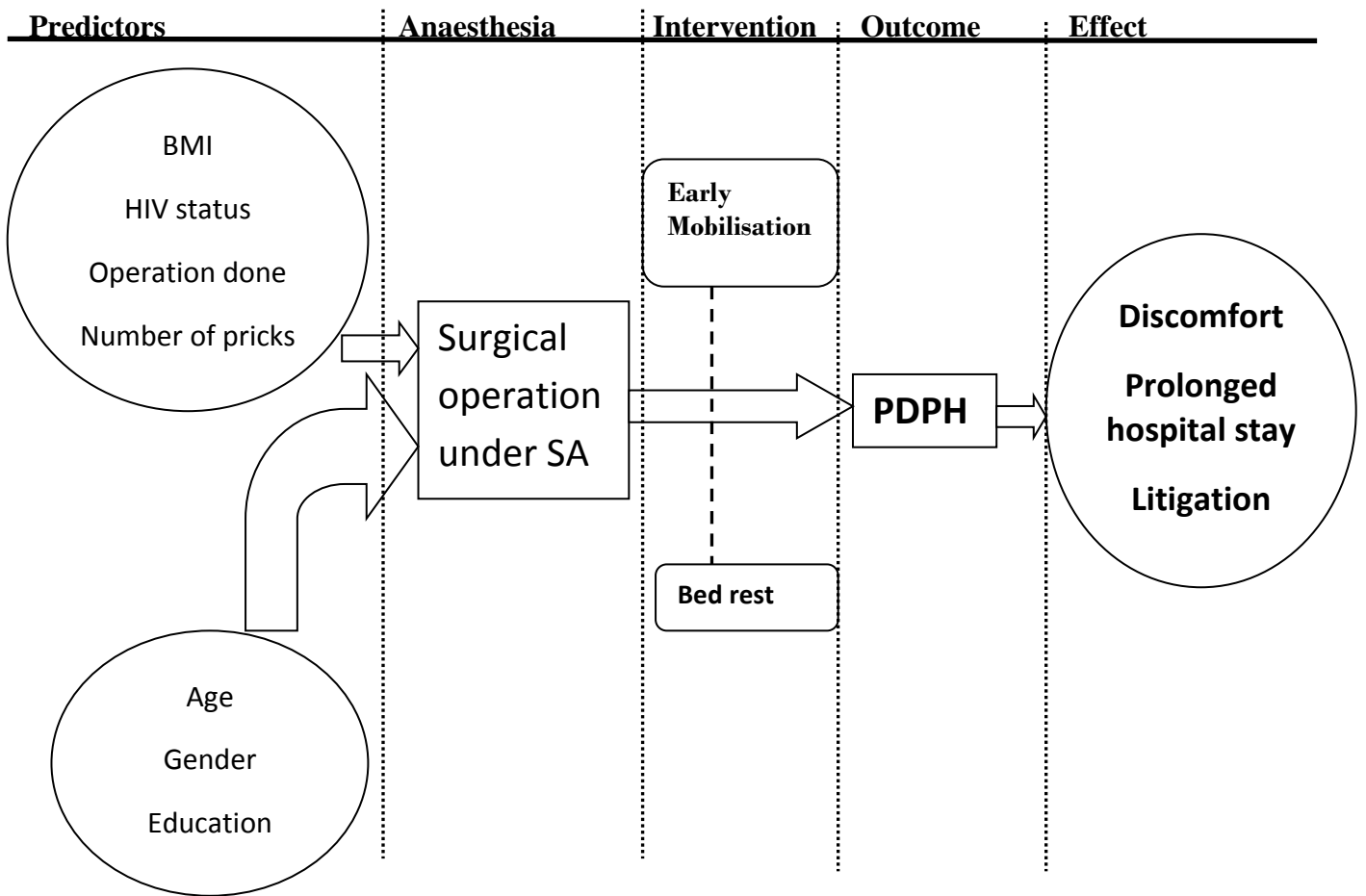
1. To determine the incidence of postdural puncture headache (PDPH) in patients given spinal anaesthesia in the study period.
2. To determine whether early mobilization increases the risk of postdural puncture headache (PDPH) in patients given spinal anaesthesia.

### **1.6 HYPOTHESIS**

NULL: There is no benefit in restricting movements in prevention of PDPH in spinal anaesthesia.

ALTERNATIVE: There are benefits in restricting movements in prevention of PDPH in spinal anaesthesia.

## 1.7 CONCEPTUAL FRAMEWORK



The figure above depicts the possible risk factors and the consequences of post spinal headache following spinal anaesthesia for major surgical operations in Nsambya hospital. Bed rest routinely used following spinal anaesthesia is thought to prevent PDPH. This study was aimed at demonstrating whether early mobilization increased the incidence of PDPH with bed rest as controls. The study was however not to investigate the consequences of the PDPH outlined above.

## CHAPTER TWO

### 2.0 LITERATURE REVIEW

#### 2.1 Historical Background

Historical reference to PDPH was recorded by August Bier in 1899, when he gave a personal account of his headache, he suffered after spinal anesthesia given to him on his request by his assistant<sup>[2]</sup>. Dr. Bier described the headache as a feeling of very high pressure in the head, accompanied by light dizziness when rising quickly from the chair. He also described the most important sign of PDPH as follows: "all symptoms disappeared immediately when I laid horizontally but came back when I got upright". Dr. Biers suggested that CSF loss caused the symptoms he experienced and his advice is to prevent the loss of CSF as much as possible, as he lost excessive CSF while receiving the experimental spinal block by his assistant who was unable to fit the syringe to the needle during the procedure.

Spinal anesthesia has enjoyed a long history of success and recently celebrated a centennial anniversary<sup>[4]</sup>. Anesthesiologists master spinal anesthesia early during training with achievement of competence (. 90% technical success rate) after only 40–70 supervised attempts<sup>[5, 6]</sup>. The ease and long history of spinal anesthesia may give the impression that it is a simple technique with little sophistication. However, much has been learned recently regarding the anatomy, physiology, pharmacology, and applications of spinal anesthesia.

#### 2.1.2 INCIDENCE

Overall incidence of PDPH after intentional dural puncture varies form 0.1-36%, the highest incidence of 36% is found after ambulatory diagnostic lumbar puncture using a 20 or 22 gauge standard Quincke spinal needle<sup>[3]</sup>. Unintentional dural puncture with large tuohy needle (16 and 18 gauge) is associated with high incidence of 70-80% PDPH. In obstetric population unintentional dural puncture is one of the common major complications. The Incidence of dural puncture in obstetrics practice in UK is 0.18 - 3.6%. Eighty percent of these patients suffer from PDPH<sup>[3]</sup>. It is suggested that the incidence in teaching centres should be less than 1%<sup>[5]</sup>.

A study of malpractice claims filed against anesthesiologists providing obstetric anesthesia care showed 12% of the claims were because of post-delivery headache in patients who received



epidural analgesia and possibly a dural puncture. This was the 3rd most common claim filed, the other injuries being maternal death and newborn brain injury<sup>[6]</sup>. The incidence of course greatly varies with the technique and equipment used. Major factors influencing the incidence are discussed later in the reviews.

### **2.1.3 PATHOPHYSIOLOGY**

Almost a century has passed after first report of PDPH in literature but exact mechanism of PDPH is still not known. Leakage of cerebro-spinal fluid (CSF) through dural puncture appears to be the main cause of PDPH and was first proposed in 1902<sup>[7]</sup>. This leakage theory however is not universally accepted but still majority of investigations favour this "leakage theory", as an explanation for PDPH.

This theory states that leakage of CSF through the dural hole causes decreased CSF pressure and volume, followed by gravity dependent downward sagging of the brain resulting in traction on the pain sensitive structure around the brain<sup>[8,9]</sup>. Recently however multi-slice sagittal magnetic resonance imaging (MRI) studies failed to show any evidence of such sagging<sup>[10]</sup>. Furthermore, patients with typical features of PDPH and normal CSF pressure have been reported<sup>[11]</sup>.

A consistent feature of PDPH is that jugular vein compression (which causes high CSF pressure) increases the severity of PDPH<sup>[11]</sup>. Intravenous caffeine and theophylline both adenosine antagonist and potent cerebrovascular constrictors relieve PDPH in upto 70% of cases<sup>[12,13]</sup>. If low CSF pressure is the reason of causing PDPH then cerebrovascular constrictors should have increased the severity of PDPH rather than decrease it. CSF is produced at an average rate of 500 ml/day, and approximately 150 ml is circulating at any given time around the brain and spinal cord. Excess fluid may be excreted via arachnoids Villi however the body cannot immediately compensate for loss of CSF (as happened after dural hole) and to restore the intracranial volume, dilatation of intracranial vessels occur.

The throbbing and orthostatic nature of headache constitutes an important symptom of cerebral

Vasodilatation and intracranial congestion of blood and supports the hypothesis that the loss of CSF causes compensatory cerebral vasodilatation resulting in PDPH<sup>[14]</sup>. In a recent study, Andra proposes that PDPH is probably a vascular type headache and epidural blood patch relieves the headache by its vaso-constrictive action<sup>[15]</sup>.

This cerebral vasoconstriction may be caused by subarachnoid spread of the injected blood. The possible role that the rich innervations of the dura matter with adrenergic, cholinergic, and peptidergic fibers may play a role in PDPH and its management with epidural blood patch requires further research to know the exact mechanism of PDPH.

#### **2.1.4 SYMPTOMS**

Postdural puncture headache is characteristically located in the frontal and or the occipital region, aggravated by the upright position and relieved by recumbence. It may be associated with nausea and vomiting, auditory and visual symptoms. Pain may radiate to the neck and neck stiffness may be present<sup>16</sup>. The diagnosis is mainly based on the relationship of headache and patient position. In the absence of postural contribution to symptoms, the diagnosis may be questioned. PDPH occurs immediately if the patient is in the sitting position and it has been demonstrated that drainage of 20 ml of CSF from a subject in the upright position with a 16g tuohy needle resulted in an immediate headache<sup>[17]</sup>. Typically, the patient complains of a severe headache with change in position (upright), pain is incapacitating, throbbing in nature accompanied by photophobia, double vision, blurred vision, dizziness, tinnitus, decreased hearing, and nausea, vomiting and not responding to minor analgesics. For the majority of patients who develop PDPH, the syndrome resolves spontaneously in a few days to a week. However there are reports of PDPH persisting for months to a year<sup>[18]</sup>.

### **2.1.5 COMPLICATIONS OF PDPH**

Neurological sequelae, following dural puncture are well recognized, the most serious although rare complication is the occurrence of transient cranial nerves palsy, and almost all cranial nerve have been implicated. Usually single nerve palsy has been reported, the nerves affected are 3<sup>rd</sup>, 4<sup>th</sup>, 6<sup>th</sup>, 7<sup>th</sup>, and 8<sup>th</sup>. Reported incidence of cranial nerve palsies is 1: 100,000 to 3.7 in 100,000 cases.

The 6<sup>th</sup> nerve is said to be most susceptible, but length alone is not the sole factor as the 4<sup>th</sup> cranial nerve is longer than the 6<sup>th</sup> cranial nerve, but is rarely affected. The abducent nerve is suggested to be vulnerable because it is relatively fixed at its entry into the cavernous sinus and at its attachment to the Pons. This nerve is most likely to be stretched due to sagging of the brain because of CSF leak<sup>[19]</sup>. Blindness following spinal analgesia has been reported in a young healthy prime gravida, who developed blindness on 1st post partum day. The blindness resolved within 48 hours and recovered completely within 7 days<sup>[20]</sup>.

Cases of subdural haematoma or cerebral haematoma have also been reported in literature. Although rare subdural haematoma or cerebral bleed can occur in previously fit, healthy patients after spinal puncture even when it was performed with a small gauge needle. The cause proposed is a constant leak of CSF, or reduction in CSF, volume could lead to brain sagging, with traction on the delicate blood vessels, causing them to rupture and later formation of a haematoma<sup>[21]</sup>.

### **2.1.6 DIFFERENTIAL DIAGNOSIS OF PDPH**

Diagnosis of PDPH should only be made when other causes of headache are ruled out. When a headache occurs after spinal or epidural anaesthesia it must be considered potentially serious and should be differentiated from other causes of headache. Awareness must be cultivated that dural puncture headache is only one of the many causes of headache in postoperative and postpartum period.

#### **2.1.6.1 TENSION HEADACHE**

It is typically a dull, persistent pain that extends over the entire head. Onset is gradual and the headache may persist for a long time. There is no relation to the position of the patient, lying for upright. Tension headache rarely effects obstetric and anesthetic management, but may signal an increased risk of post partum depression.

### **2.1.62 MIGRAINE HEADACHE**

Migraine headache is classically described as unilateral throbbing headache, sometimes accompanied by nausea and vomiting and there is no relief in the supine position. Careful questioning and physical examination needs to be done for other causes of headache<sup>[22]</sup>.

### **2.1.63 CAFFEINE WITHDRAWAL**

It may lead to headache in a moderate regular consumer; this could be a cause of PDPH, though appears to be overlooked. It should be considered in the differential diagnosis.

### **2.1.64 LACTATION HEADACHE**

After child birth, headache is associated with increased plasma vasopressin concentration. This gives rise to episodes of intense headache during breast feeding, especially in those women who are known to suffer from migraine<sup>[23]</sup>.

### **2.1.65 BRAIN TUMOUR**

The headache is dull in character rather than throbbing, is mostly accompanied by nausea, vomiting, seizures may also occur. There are usually focal signs and there is evidence of increased intra-cranial pressure<sup>[24]</sup>.

### **2.1.66 SUBDURAL HAEMATOMA**

In rare instances dural puncture is associated with the subsequent development of subdural haematoma which is followed by symptoms of PDPH. Leakage of CSF and decreased ICP causes stress on the cerebral vessels which can precipitate bleeding. Neurological signs include evidence of raised ICP i.e. headache, somnolence, vomiting and confusion with focal abnormalities<sup>[25]</sup>.

### **2.1.67 SUBARCHNOID HEAMORRAHGE**

Headache produced by SAH is sudden, severe and mainly in the occipital region, the symptoms include vomiting neck stiffness and decreased level of consciousness or coma.

### **2.1.68 CORTICAL VEIN THROMBOSIS (CVT)**

Headache may be caused by cortical vein thrombosis. The headache is severe and throbbing in nature, there may be focal signs with, seizures and coma may follow<sup>[26]</sup>.

### **2.169 HYPERTENSION**

Eclampsia is a form of hypertensive encephalopathy occurring in pregnancy which includes headache, visual disturbances, nausea, vomiting, seizures, stupor and sometimes coma.

### **2.1.70 MENINGITIS**

There is severe headache in meningitis, and this is accompanied by fever, neck stiffness, and a positive kernig's sign. There is lethargy, confusion, vomiting, seizures and skin rash may occur.

### **2.1.71 PNEUMOCEPHALUS**

The subdural injection of air used for identification of epidural space may cause sudden headache, accompanied by neck and back pain. It is also positional in nature, worse on sitting-up and relieved by lying down.

### **2.1.72 SPONTANEOUS INTRACRANIAL HYPOTENSION (SIH)**

Spontaneous Intracranial hypotension is a condition with symptoms and pathophysiology indistinguishable from the PDPH. This is a rare clinical entity and is thought to be due to rupture of a perineural cyst of the spine<sup>[27]</sup>. Whenever headache after regional anesthesia does not present the classic symptomatology, of which postural character is essential or does not present with classic evolution, neurological evaluation must be undertaken without delay. A contrast CT or MRI scan is sometimes necessary before therapeutic measures can be adopted.

## **2.2 Factors influencing PDPH**

The main factors influencing PDPH can be categorized as:

1. Characteristics of patient population
2. Characteristic of needle used
3. Puncture technique

### **2.2.0 AGE**

Certain patient populations are at an increased risk for development of post dural puncture headache. Patient's age 20-40 years are most susceptible whereas the lowest incidence occurs after fifth decades<sup>[28,29]</sup>. The lesser incidence of PDPH in elderly individual is due to decrease in the elasticity of cranial structures, which occurs in the normal aging elasticity of cranial structures, which occurs in the normal aging process, and reduction in overall pain sensitivity. Definitive statements about PDPH in patients younger than 10 years of age are not possible. In this patients population PDPH is rarely reported suggesting a lower incidence compared with adults<sup>[30]</sup>.

This could be explained by lower CSF pressure in infants and children than adults and also the lower hydrostatic pressure in lumbar regions generated by the upright position in children<sup>[31]</sup>.

### **2.2.1 GENDER**

Women are more likely to be affected than men when risk is adjusted for age. In the series reported by Vandane and Dripps, women had twice the incidence i.e., 14% of PDPH compared with men i.e., 7%. Some suggested that this difference was because of a large number of obstetric patients in the women's group. Nevertheless even after removal of these cases women still had higher (12%) incidence compared to men (7%)<sup>[32]</sup>. Others suggested that generally lower age of female patients compared with male patients accounts for the association between PDPH and gender<sup>[40]</sup>.

### **2.2.2 OBSTETRIC PATIENTS**

Parturition constitutes the highest risk category for PDPH, to which a number of factors contribute. Generally accepted incidences in these patients have been reported up to 38% but in some studies vary between 0%-30%<sup>[32]</sup>. Increase in CSF pressure from bearing down during vaginal delivery and postpartum decreases in intra abdominal and peridural pressure may all contribute to increase in the incidence of PDPH in this patient population. However, Ravindran et al suggest that bearing down at the time of delivery is not a factor for high incidence<sup>[33]</sup>.

The concept that pregnancy is a risk factor for PDPH is not supported by contemporary practice. After spinal anesthesia the incidence of PDPH in the parturient currently is similar to that reported in young men and non-pregnant women<sup>[34]</sup>. This issue is unlikely to be resolved by a randomized prospective trial because of a large number of subjects needed for this study.

### **2.2.3 CHARACTERISTIC OF NEEDLE USED**

There is direct correlation between needle size and risk of PDPH. Vandam and Dripps noted that the incidence ranged from 18% with a 16 gauge needle to 5% with 26 gauge needle whereas the overall risk of PDPH was 11% in 11000 cases of spinal anesthesia<sup>[18]</sup>. There is enough evidences that both needle size, and tip design impact on the incidence of PDPH. The results of a meta analysis of 450 articles showed reduction of PDPH when: (a) small spinal needle was used compared with a large needle of the same type and (b) non-cutting spinal needles rather than cutting needles were used, unless the discrepancy in needle size is very large<sup>[35]</sup>.

With the quincke needle the incidence of PDPH is directly related to the size of the needle used<sup>[36]</sup>. The pencil point or blunt tip needles like whitacre needle are associated with lower PDPH rates because they are less traumatic to the longitudinal fibers of dura, separating them and this produces a small rent with reduced CSF leakage. The rate of PDPH with 25 gauge whitacre needle as 1.2% in comparison to 27 gauge cutting needle as 2.7%<sup>[37]</sup>

A randomized comparison of 25 gauge Whitacre and Quincke needle revealed a significantly lower incidence of PDPH in the whitacre group 8.5% versus 3%<sup>[38]</sup>. Some evidence in vitro suggests that fluid leak through a dural hole is lower with pencil point than with beveled needles. In a randomized trial of 24 gauge sprotte and 25 gauge quincke needle in patients receiving spinal anaesthesia for cesarean section. There were no cases of PDPH in the sprotte group but there was 14.5% incidence of PDPH in the quincke group<sup>[39]</sup>. Recently a modification of the Quincke needle has been made available, known as atraucan needle. It has a cutting point and double bevel which are intended to cut a small dural hole and then dilate it<sup>[40]</sup>. In current practice its role has not been clear.

#### **2.2.4 PUNCTURE TECHNIQUE**

Orientation of needle bevel piercing the dura, angle of insertion and number of punctures are important factors in puncture technique. The orientation of the bevel of a spinal needle parallel to the long axis of the spine produced less dural trauma than occurred when the bevel is inserted perpendicularly<sup>[41]</sup>. The dura has been described as longitudinal in direction, however recently electron microscopy has revealed that the dural structure is far complex than was originally was supposed. Fink and Walker noted that the dura consists of multidirectional interlacing collagen fibers and both transverse and longitudinal elastic fibres<sup>[42]</sup>. The insertion of the needle with the bevel parallel to the long axis of the spine most likely results in less tension on the dural hole.

Accidental dural puncture occurred in 41 women (2.63%). Twenty women with the needle bevel oriented perpendicular and 21 with the needle bevel inserted parallel to the longitudinal dural fiber. Fourteen women out of 20 (70%) developed PDPH in perpendicular group and 5 out of 21 women (24%) suffered PDPH in the longitudinal group. These data suggest that the orientation of the epidural needle is not a factor in avoiding an accidental dural puncture but is crucial in diminishing the resultant PDPH<sup>[43]</sup>.

### **2.2.5 ANGLE OF INSERTION**

At least one in vitro study suggests that the insertion of the needle at an acute angle results in decreased leakage of CSF<sup>[43]</sup>. An oblique angle of penetration theoretically creates a flap valve that tends to seal the perforation in dura but important clinical studies substantiating this point are lacking.

### **2.2.6 NUMBER OF PUNCTURE**

There are reports available addressing the issue whether multiple dural punctures influences the frequency of PDPH. Lybecker et al did not find a significant association between the number of punctures and the frequency of PDPH after multivariate analysis<sup>[44]</sup>. However recent analysis of prospective data on 8,034 spinal anesthetic patients showed increase in the incidence of PDPH with repeated dural puncture, this confirms the assumption that a second dural puncture increases the risk of PDPH<sup>[45]</sup>.

## **2.3 Applied anatomy**

### **MENINGES**

Many anatomic structures important for spinal anesthesia have only recently been investigated. The arachnoid membrane is a structure of obvious interest, as spinal agents must be delivered within its confines. The arachnoid membrane is composed of overlapping layers of epithelial cells connected by tight junctions <sup>[46]</sup>. This anatomic arrangement allows the arachnoid membrane, not the dura, to function as the principal meningeal barrier (90% of resistance) to materials crossing in and out of the cerebrospinal fluid (CSF)<sup>[47]</sup>.

A functional proof of the arachnoid's importance as gatekeeper to the CSF is that spinal CSF resides in the subarachnoid and not subdural space.



The arachnoid membrane serves not only as a passive container of CSF but also actively processes and transports agents attempting to cross the meninges. Recent studies demonstrated that metabolic enzymes are expressed in the arachnoid that can affect agents (e.g., epinephrine) and neurotransmitters important for spinal anesthesia (e.g., acetylcholine)<sup>[48]</sup>. Active transport of compounds across the arachnoid membrane occurs in the area of the neural root cuffs. Here, unidirectional transport of materials from the CSF into the epidural space occurs and may contribute to clearance of spinal anesthesia agents. Another potential clinical consideration of the lamellar structure of the arachnoid is easy separation of the arachnoid membrane from the dura during spinal puncture. This mechanical arrangement allows easy subdural deposition of spinal agents despite the free return of CSF during spinal injection, which may help to explain individual effects of spinal anesthesia<sup>[49]</sup>.

### **2.3.1 SPINAL CEREBROSPINAL FLUID VOLUME**

After injection of spinal anesthetics, dilution with the CSF occurs before arrival at effector sites in the central nervous system. Thus, individual variation in lumbosacral volumes of CSF and distribution within this volume will affect spinal anesthesia. Recent use of magnetic resonance imaging (MRI) demonstrates great variability between individuals in volume of lumbosacral CSF, with a range of 28–81 ml<sup>[50]</sup>. Interestingly, obese individuals have substantially less CSF (~10 ml less), which is partly caused by compression of the neural foramina. Clinical correlation between volume of lumbosacral CSF and spinal anesthesia with hyperbaric lidocaine and isobaric bupivacaine is excellent, with CSF accounting for 80% of the variability for peak block height and regression of sensory and motor block<sup>[51]</sup>

Unfortunately, volume of lumbosacral CSF does not correlate with external physical measurements other than weight ( $r = 0.4$ ,  $P, 0.05$ ); therefore, volume cannot be easily estimated from physical examination<sup>[51]</sup>.

Other important considerations include the observation on MRI that the CSF is not a “still lake” of fluid but vigorously oscillates with arterial pulsations. These wavelike movements may be another important factor in distribution and clearance of spinal agents and may influence neurotoxicity from exposure to concentrated agents.

### **2.3.2 SPINAL NERVE ROOTS**

The target sites of spinal anesthetics are the spinal nerve roots and spinal cord. In a similar fashion to volume of CSF, individual variability in anatomy of spinal nerve roots may also explain variability in spinal anesthesia<sup>[52]</sup>. Recent autopsy and microscopic studies observed great inter individual variability in size of human nerve roots. For example, the range of the posterior nerve root of L5 is 2.3–7.7 mm<sup>3</sup>. Other interesting anatomic findings are the relatively larger size of dorsal nerve roots, compared with ventral, with packaging into easily separable strands. Although a larger dorsal nerve root would seem more impenetrable to local anesthetics, the separation of the dorsal root into component bundles creates a much larger surface area for local anesthetic penetration than the single smaller ventral nerve root. This anatomic finding may help explain the relative ease of sensory versus motor block. Finally, recent microscopic and endoscopic examination of the subarachnoid space reveals the presence of numerous membranes surrounding nerve roots and ligaments within the arachnoid that potentially compartmentalize spinal CSF<sup>[53]</sup>.

These partitions may help to concentrate local anesthetics near nerve roots and augment spinal anesthesia but could also impede communication of CSF between dorsal and ventral nerve roots, thus again explaining relative difficulty of achieving motor block.

## **2.4 Applied physiology**

### **THERMOREGULATION**

Mild perioperative hypothermia is associated with an increased incidence of myocardial ischemia, cardiac morbidity, wound infection, blood loss, and transfusion requirements. Both general and regional anesthesia impairs temperature homeostasis to a similar degree<sup>[54]</sup> and careful monitoring and active maintenance of temperature is a simple means to prevent morbidity.

The effects of spinal anesthesia on temperature homeostasis have been well studied, and there are three main mechanisms causing core hypothermia.

The first is redistribution of central heat to the periphery caused by vasodilatation from sympathetic block. This effect is maximal during the first 30–60 min, causes a decrease in core temperature of approximately 1–2°C, and depends on extent of sensory block and patient age <sup>[54]</sup>.

The second mechanism is loss of thermoregulation characterized by reduced shivering and vasoconstriction thresholds during spinal anesthesia. This abnormal tolerance for hypothermia occurs because of subjective warmth exceeding the actual surface temperature increase from sympathectomy. This exaggerated sense of warmth is proportional to extent of sensory and sympathetic block and decreases thresholds for shivering and vasoconstriction.

Thus, hypothermia may occur during spinal anesthesia without a conscious perception of cold<sup>[55]</sup>. Finally, with loss of thermoregulatory vasoconstriction below the level of the sympathetic block, there is increased heat loss from vasodilatation. Spinal anesthesia will predictably cause core hypothermia within 30–60 min, and patients should be monitored and actively warmed if needed <sup>[56]</sup>.

Unfortunately, a recent survey of practicing members of the American Society of Anesthesiologists revealed that only 33% of practitioners use temperature monitoring during regional anesthesia <sup>[57]</sup>. Furthermore, temperature was most commonly monitored on a surface site.

## **SUPRASPINAL EFFECTS ON CONSCIOUSNESS**

There has been a recent convergence in mechanisms of general and spinal anesthesia. Minimum alveolar concentration, a traditional measure of inhalational agent potency for depth of anesthesia, appears to have a primary mechanism in the spinal cord. In contrast, central neuraxial anesthesia may have direct effects on suppression of consciousness, and multiple studies have observed that patients appear drowsy after spinal anesthesia despite lack of sedative medications <sup>[58]</sup>. Correspondingly, both spinal and epidural anesthesia reduce the hypnotic requirements of midazolam, isoflurane, sevoflurane, and thiopental in surgical patients and laboratory studies.

## 2.5 Treatment of PDPH

Intravenous caffeine sodium benzoate has been in use, off and on, for approximately half a century as a treatment for PDPH. One regimen was to put 500 mg of caffeine sodium benzoate in one liter of intravenous fluid and infuse this over one hour. It could be repeated every 8 hours. Presumably, the cerebral vasoconstrictive effects of caffeine help attenuate the vascular distention, providing analgesia. While some investigators reported very good results with intravenous caffeine sodium benzoate, others found it to be no better than placebo. These days it is difficult to obtain caffeine sodium benzoate.

It was showed that 300 mg of oral caffeine would provide some temporary analgesia, but while the relief was better than placebo, it was often temporary and there was a high recurrence rate<sup>[59]</sup>. As a practical matter, oral caffeine is not always useful in this situation, since it involves taking multiple 300 mg doses of caffeine throughout the day. A time-release preparation of theophylline worked somewhat better, presumably because of its longer duration of action as well as its more potent vasoconstrictive effect on cerebral vessels<sup>[60]</sup>.

Sumatriptan 6 mg subcutaneously has been very successful in some studies in relieving the pain of a PDPH<sup>[61]</sup>. It remains to be seen whether the oral form of this medication works as well as the subcutaneous route. An epidural blood patch (EBP) remains the standard against which all other treatments for a PDPH are compared. By creating a blood clot over the hole in the dura, the CSF leak can be slowed or halted entirely. As with the more conservative treatments, the epidural blood patch buys time. While the clot is in place, the hole is closing.

By the time the clot has resolved, the hole has usually reduced in size to the point where the symptoms of the PDPH have either disappeared or become tolerable. Of course, should the clot become dislodged during this period, the headache may return.

The pain relief from an EBP is often immediate. If the EBP worked simply by plugging the dural leak, one would expect that the CSF deficit would take a much longer time to be replenished. Therefore, a second mechanism of action may be at work. It is possible that the EBP also works by increasing pressure in the spinal cord.

When blood patches were first performed, small volumes (3 - 8 ml) of autologous blood were used. These days, the common practice is to use 15 to 20 ml of blood in the patch. This enables a greater spread of the blood through the epidural space to ensure that it covers the dural puncture. With these volumes, the EBP is said to be effective more than 95% of the time<sup>[62]</sup>.

A headache may recur following an EBP, but the EBP is so effective in the treatment of a PDPH, that if the patient fails to obtain any relief, the original diagnosis should be questioned. Headaches that result from other etiologies are sometimes mistaken for a PDPH<sup>[63]</sup>.

Although the EBP is usually thought of as a benign procedure, it is not without its complications. Fortunately, most of these are relatively minor. Approximately 35% of patients who receive an EBP report back pain<sup>[66]</sup>.

Neck pain, leg pain, paresthesias, radiculitis, fever, and temporary cranial nerve palsies have all been reported following the administration of an EBP. It is not uncommon to obtain a second wet tap when attempting to place an EBP.

Other substances besides autologous blood have been used in the epidural space in an attempt to either "patch" the hole in the dura or diminish the CSF leak. Historically, the oldest of these is normal saline, the "saline patch." There have been many regimens proposed for this therapy. One is to inject 40 ml of saline into the epidural space, and follow this with an infusion of 40 ml/hr over the next 12 to 24 hours. Others simply use the initial injection and forego the subsequent infusion. Although effective in the short term, a high recurrence rate of PDPH symptoms is often reported with this method<sup>[64]</sup>.

Low molecular weight dextran has been used in some studies as a substitute for the EBP. Injecting 20 - 30 ml of dextran has been highly successful in treating the headaches<sup>[33]</sup>. In one study, a 20 ml of dextran given prophylactically as a "patch" was effective in preventing PDPHs<sup>[65]</sup>.

Gelatin powder (Gelfoam) and fibrin glue have both been used as epidural patches for postdural puncture headaches. They may be effective, but are significantly more difficult to administer than dextran.

## **CHAPTER THREE**

### **3.0 RESEARCH METHODOLOGY**

#### **3.1 STUDY DESIGN**

The study was an Open Randomized Controlled trial that was carried out between August and December 2014.

#### **3.2 STUDY SETTING**

The study was carried out at St Francis Hospital Nsambya, a Faith Based, Private not for Profit Hospital in Kampala Uganda.

It is the teaching hospital for the Mother Kevin Postgraduate School of Medicine a college of the Uganda Martyr's University

The Hospital has four Departments; General surgery, Internal medicine, Obstetrics and Gynaecology and Paediatrics among some of the general disciplines subspecialties are being created. The Capacity of the hospital is 250 beds

Patients with surgical, obstetrics and gynecological conditions are seen in the General Outpatients department by Medical Officers and intern doctors. After admission patients are re-evaluated by a surgical resident who later consults a Consultant in a specialized field if necessary.

The Department of Surgery offers general surgical services together with other super specialized surgical services like Urology, Cardiothoracic, Neuro surgery, Paediatrics and Plastic surgery.

### **3.3 POPULATION**

#### **3.31 Target population**

All patients who had surgical, obstetric or gynecological operations done under spinal anesthesia at Saint Francis Hospital Nsambya during the study period were enrolled.

#### **3.32 Accessible population**

All patients who had surgical operation carried upon them under spinal anesthesia during the study period.

### **3.33 Study population**

The study population was from the General Surgery and Obstetrics and Gynaecology Departments. It included all patients who had surgery under spinal anaesthesia and had consented to participate in the study

## **3.4 SELECTION CRITERIA**

### **3.41 Inclusion**

Participants:

- Patients who were at least 15 years of age (and above) who were able to consent and easy to cooperate for assessment of pain and those with care takers that could give consent.
- Emergency or elective surgical intervention.
- Patient who had a phone contact.

### **3.42 Exclusion.**

The exclusion criteria included patients with;

- Use of oral opioids.
- Regular use of nonsteroidal anti-inflammatory drugs.
- Simultaneous general anesthesia.
- Alcohol or drug abuse.
- History of migraine or any chronic headache preoperatively or on the morning of surgery.
- Patients, who were disabled for example deaf, dumb where PDPH may be difficult to assess.
- Patients who had ever suffered from an epidural puncture headache.

## **3.5 RANDOMIZATION**

### **3.51 Sequence Generation**

This was a block (restricted) randomization. A computer-generated randomization list (based on the closed-sequence method) was made by a statistician.

### **3.52 Allocation**

The computer-generated randomization list drawn up by the Statistician was not revealed to the investigators until after the participant recruitment was completed. The assignment (written on small cards with the codes **G<sub>MOB</sub>** or **G<sub>REST</sub>** for early mobilization or restricted movements respectively) was enclosed in sequentially numbered opaque, sealed envelopes. Thus, each envelope had on the outside only a sequential number.

The envelopes were arranged in a sequential order which was followed from the top (serial number 01) of the batch to the bottom (serial number 116) and were stationed in the operation theatre. Only the statistician and PI knew what the number/code signified.

Patients with planned surgical intervention under spinal anesthesia were interviewed and clinically assessed by the Principal Investigator (PI). The purpose of the study and the methods of treatment were carefully explained to the patients individually. They were allowed to ask questions freely to ensure that they had understood.

Screening for suitability for surgery included history taking, physical examination, requesting for and reviewing the laboratory tests was done. This was aimed at recording the key research variables and major co-morbidities. Those who did not satisfy the inclusion criteria and had other medical problems were offered care suitable to their conditions.

### **3.53 Implementation**

Participants were assigned on an individual basis to both early mobilization and bed rest arms. The Research Assistant was responsible for picking the envelopes for the patient due for operation. The serial numbers on the envelopes corresponded to the serial numbers of the participants as they consecutively got enrolled into the study. At the time of operation the research assistant would pick the corresponding envelope. The envelope would then be given to the theatre staff that would open and remove the small card with the code.



The surgeon (PI) would be told the code, and thus reveal the arm to which the patient belonged, at the time of administration of anaesthesia. The participant would then be treated accordingly. The used envelopes were then securely kept in a cabinet in the theatre.

### 3.6 SAMPLE SIZE

**Formula: used by Casagrande, Smith and Pike for comparing two proportions<sup>[35]</sup>**

Defined  $Z_P$  to be the upper 100(1-p) percentile of the standard normal distribution,

$m$  be the required sample size from the first population,

$rm$  be the required sample size from the second population,  $0 < r < \infty$

$$\delta = |P_2 - P_1|, \bar{P} = \frac{P_1 + rP_2}{r+1} \text{ and } \bar{Q} = 1 - \bar{P}$$

$$m = \frac{m'}{4} \left[ 1 + \sqrt{1 + \frac{2(r+1)}{rm'\delta}} \right]^2 \quad (*)$$

$$\text{where } m' = \frac{\left[ z_\alpha \sqrt{(r+1)\bar{P}\bar{Q}} + z_\beta \sqrt{(rP_1Q_1 + P_2Q_2)} \right]^2}{r\delta^2}$$

$$N = (r+1)m$$

Note: (\*) is corrected with continuity.

#### Notations:

$\alpha$ : The probability of type I error (significance level) is the probability of rejecting the true null hypothesis.

$\beta$ : The probability of type II error (1 – power of the test) is the probability of not rejecting the false null hypothesis.

| <b>Variables</b> | <b>Descriptions</b>               |
|------------------|-----------------------------------|
| A                | Significance level                |
| 1- $\beta$       | Power of the test                 |
| P <sub>1</sub>   | Success proportion in arm 1       |
| P <sub>2</sub>   | Success proportion in arm 2       |
| R                | Ratio of arm 2 to arm 1           |
| M                | Sample size for arm 1             |
| N                | Total sample size for arm 1 and 2 |

With significance level  $\alpha=0.05$ , equal sample size from two proportions ( $r=1$ ), the probability **P<sub>1</sub> = 0.3** and **P<sub>2</sub> = 0.5** were considered sufficiently different to warrant rejecting the hypothesis of no difference. Then the required sample size for two arms to achieve an 80% power ( $\beta=0.2$ ) was determined by; **M = 55** and **N = 110**

### **3.7 Sampling method**

Patients that fulfilled the inclusion criteria were enrolled consecutively until the required sample size was attained.

### **3.8 PROCEDURE**

Patients eligible for study were seen from the emergency, labour ward, the General Surgical, Antenatal and Gynaecology wards. The Principal Investigator and trained Research Assistants visited and interviewed them using a Study Protocol (see appendix) for screening for the inclusion criteria

Patients fulfilling the Inclusion Criteria were subjected to a standard clinical examination that included obtaining the patient's demographic characteristics, history, physical examination, relevant laboratory and imaging tests and the diagnosis.

In the operating room, a Research Assistant assigned to theatre would pick the next envelop in the series from the stack in the designated area. He would cross-check to ensure that the number on the envelop corresponded with that of the patient in the order of enrolment in the study.

Following confirmation, the envelop was given to the theatre staff who opened it to reveal the arm of the study of the patient. It was documented in the patients' postoperative notes for ward team to implement the spinal anaesthesia postoperative protocol.

A standard 25 Crawford gauge spinal needles were used to administer the anaesthesia. The bevel of the spinal needle was directly laterally so that the Dural fibers that run longitudinally were spread rather than transected. In the median approach the dural puncture was performed in the L2-3, L3-4, or L4-5 interspaces, with the patients in the sitting position and hyperbaric Bupivacaine was the anesthetic drug which was used. All patients were preloaded with one litre of intravenous fluids.

On return to the ward a patient recovery chart was opened, the patients were monitored for the return of motor and sensory function of the limbs. When fully recovered an independent, Assessor (a Surgeon) was informed. Using the assessment PDPH tool would make or exclude a diagnosis of PDPH. (Only position-dependent headaches, aggravated by sitting or upright position and relieved by lying down, and headaches with bifrontal or occipital location, frequently involving the neck and upper shoulders, were regarded as PDPH. Other types of headache were considered non-specific and not PDPH).

The patient were assessed twice daily till discharge. Patients who developed PDPH were treated with Paracetamol with or without Imipramine and irrespective of the arm of intervention were all put on bed rest. Patients were followed up at one week after discharge through phone calls.

### **3.9 STUDY VARIABLES**

#### **Predictor variables**

- Demographic characteristics: Age, BMI and Occupation.
- HIV status.
- Number of prick

#### **Outcome variables**

- Headache

### **3.91 DATA MANAGEMENT**

Data was collected using a standardized, interviewer-administered questionnaire. Assessment of the patient for the key outcomes was done by the Aesearch assistants. The data was edited for completeness, cleaned, coded and entered into a computer using the Epidata-Entry 3.1 and then exported to SPSS statistical package for analysis.

### **3.92 DATA ANALYSIS**

#### **3.93 ASSESSMENT OF ACCURACY OF RANDOMIZATION**

The closed sequence method of random number generation (RNG) was used. The output from the RNG was checked to ensure that the sequence showed no evidence of non-randomicity. This was done by checking the numbers for independence to ensure that there were no particular sequential patterns. The data was not checked for equiprobability, since closed sequence generation inherently provided for equiprobability.

The statistical test used for these checks was the Chi-square Contingency Table test (for independence). Independence was assumed when the two-tailed probability associated with Chi-Square was greater than 0.10 (i.e., there was no evidence of a significant deviation from randomness).

Socio-demographics and other baseline characteristics were assessed for differences in their distribution in each of the intervention arms, using statistical tests of significance (level of significance set at a two-tailed  $P < 0.05$ ).

#### **3.94 BASELINE DEMOGRAPHICS AND CLINICAL CHARACTERISTICS OF THE TWO GROUPS**

The baseline information was presented effectively in Tables. For numerical variables, their variability along with average values were reported for each group, and then summarized by mean or standard deviation, or median and ranges if asymmetrically distributed. Categorical variables were reported as numbers and proportions. All data are expressed as mean  $\pm$  standard deviation (SD). Statistical analysis of the data was performed with SPSS 15 statistical software (Cary, NC, USA), and comparisons between the groups were done using the Chi-square test. A  $P < 0.05$  was considered significant.

### **3.95 STOPPING RULES**

The results of the study were reviewed (interim analysis) after two months from the start of the trial to enable the study to be stopped early if early mobilization caused headache to the participants in a statistically significant manner in order not to subject patients to extra risk.

The level of significance was set at P value of 0.05 and was calculated according to the O'Brien-Fleming stopping boundaries. However, overwhelming efficacy of one intervention was not to be considered a reason for termination of this study.

### **3.96 QUALITY ASSURANCE**

- The spinal anaesthesia was administered by senior anaesthetic officers who were pre trained and had experience in the procedure.
- A standardized and pretested questionnaire was used.
- A statistician helped the Principal Investigator in data analysis.
- All the patients got the same anesthetic agent administered using the uniform gauge spinal needle with the same direction of the bevel.

### **3.97 DISSEMINATION OF RESULTS**

1. The results of the study will form the basis of the Dissertation to be submitted in partial fulfillment for the award of the Degree of Master of Medicine (Surgery) of Uganda Martyrs University.
2. Copies will be availed to the Department of Surgery, Mother Kevin Postgraduate Medical school of Uganda martyrs University; Research and Ethics Committee, University Graduate School; and Nsambya Hospital Management.
3. It is hoped that the study will be published in (an) appropriate surgical journal(s).

### **3.98 ETHICAL CONSIDERATIONS**

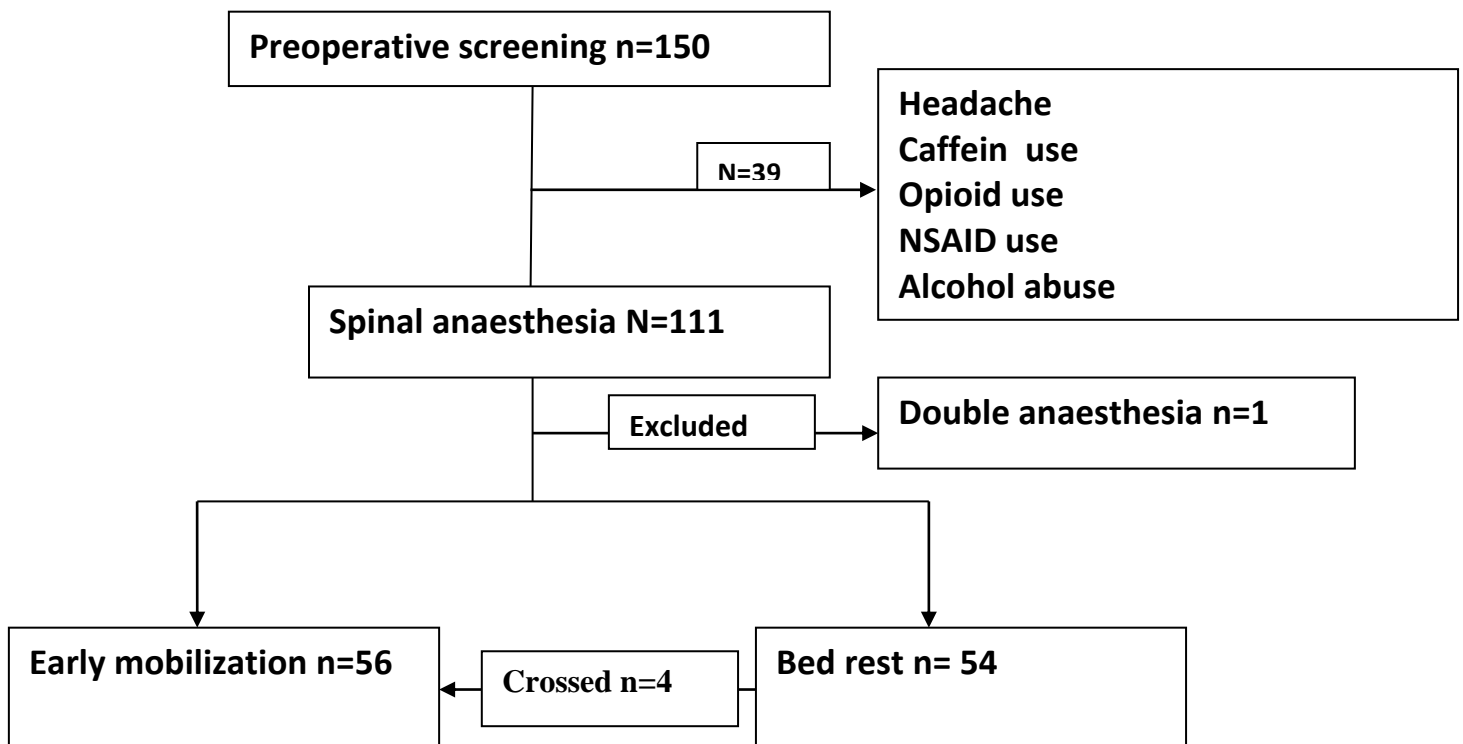
1. Approval to carry out the study was sought from the Department of Surgery, Nsambya Hospital, Mother Kevin Postgraduate Medical School of Uganda Martyrs University, Research and Ethics Committee, and Uganda National Council for Science and Technology.

## CHAPTER FOUR:

### DISPLAY AND INTERPRETATION OF RESULTS

#### 4.0 INTRODUCTION

A total of 110 participants underwent operations under spinal anaesthesia between the periods of December 2014 to February 2015. Those who fulfilled the eligibility criteria were consecutively recruited into the study and were randomly assigned to two arms, early mobilization and bed rest. The participants were assessed for the development of post spinal headache at least once during the different times. The findings are summarized as below.





#### 4.1 DESCRIPTION OF THE STUDY POPULATION

**Table 1: Description of the study population**

| <b>Variable</b> | <b>Category</b> | <b>Frequency</b> | <b>Percentage</b> |
|-----------------|-----------------|------------------|-------------------|
| Age(years)      | Less than 30    | 48               | 43.6              |
|                 | 30-39           | 50               | 45.5              |
|                 | 40-49           | 5                | 4.5               |
|                 | 50-59           | 2                | 1.8               |
|                 | 60 and more     | 5                | 4.5               |
| Gender          | Female          | 87               | 79.1              |
|                 | Male            | 23               | 20.9              |
| Occupation      | Formal          | 43               | 39.1              |
|                 | Informal        | 56               | 50.9              |
|                 | Unemployed      | 11               | 10.0              |
| Tribe           | Bantu           | 94               | 85.4              |
|                 | Luo             | 9                | 8.2               |
|                 | Others          | 7                | 6.4               |
| BMI             | Normal          | 12               | 10.9              |
|                 | Overweight      | 60               | 54.5              |
|                 | Obess           | 38               | 34.5              |
| HIV serology    | Positive        | 15               | 13.6              |
|                 | Negative        | 93               | 84.5              |
|                 | Unknown         | 2                | 1.8               |

Of the 110 participants in the study, 87(79.1%) were females. Bantu ethnicity comprised of 94(85.4%), the majority of participants were overweight 60(54.5%). The age bracket of (30-39 yrs) was the majority comprising of 45.5% and the least age bracket was (50-59 yrs) 1.8%. HIV sero positive participants were 15(13.6%) while seronegative participants were 93 (84.5%).

**Table 2: Classification and types of operations among the study participants**

| Variable                    | Category           | Frequency | Percentage |
|-----------------------------|--------------------|-----------|------------|
| Classification of operation | Emergency          | 62        | 56.4       |
|                             | Elective           | 48        | 43.6       |
| Type of operation by region | Laparotomy         | 13        | 11.8       |
|                             | Caesarian section  | 72        | 65.5       |
|                             | Perineum and groin | 14        | 12.7       |
|                             | Trauma orthopedics | 9         | 8.2        |
|                             | Others*            | 2         | 1.8        |

Others\*; varicose vein stripping 1, excision of a melanoma in the foot 1.

Emergency operations were the most performed surgery accounting to 62(56.4%) as compared to elective operations (48)43.6%. Laparotomy defined in this context as abdominal operations other than caesarian sections were 14(11.8%), caesarian sections were 72(65.5%), perineum and groin operations were 14(12.7%), trauma and orthopedic operations were 9(8.2%) and other operations not classified as above were 2(1.8%). Caesarian sections represented most of the emergency operations done, 40 (64%) the rest of the operations in the emergency category were obstructed inguinal hernia and trauma of the lower limbs. One participant who had venous stripping was an obese Luo in the age bracket of 60 years. The melanoma excision was done in a 30 year female from Bantu ethnicity. Trauma and orthopaedic cases were mostly in the age bracket of less than 30 years with a male preponderance of 7 (78%)

## 4.2 COMPARING THE CHARACTERISTICS OF THE TWO GROUPS

**Table 3: Comparing characteristics of the two groups**

|                             | Category           | Early mobilization | Bed rest | Crossed | P value |
|-----------------------------|--------------------|--------------------|----------|---------|---------|
| Age(years)                  | Less than 30       | 19                 | 29       | 00      | 0.008   |
|                             | 30-39              | 30                 | 18       | 02      |         |
|                             | 40-49              | 3                  | 01       | 01      |         |
|                             | 50-59              | 00                 | 01       | 01      |         |
|                             | 60 and more        | 04                 | 01       | 00      |         |
| Gender                      | Female             | 42                 | 42       | 3       | 0.582   |
|                             | Male               | 14                 | 8        | 1       |         |
| Occupation                  | Formal             | 24                 | 16       | 3       | 0.492   |
|                             | Informal           | 27                 | 28       | 1       |         |
|                             | Unemployed         | 5                  | 6        | 0       |         |
| Tribe                       | Bantu              | 49                 | 42       | 3       | 0.659   |
|                             | Luo                | 3                  | 5        | 1       |         |
|                             | Others             | 4                  | 3        | 0       |         |
| BMI                         | Normal             | 8                  | 4        | 0       | 0.059   |
|                             | Overweight         | 30                 | 30       | 0       |         |
|                             | Obess              | 16                 | 16       | 4       |         |
| Classification of operation | Emergency          | 35                 | 25       | 2       | 0.479   |
|                             | Elective           | 21                 | 25       | 2       |         |
| Type of operation           | Laparatomy         | 5                  | 7        | 1       | 0.801   |
|                             | Ceaserian section  | 35                 | 34       | 3       |         |
|                             | Perineum and groin | 10                 | 4        | 0       |         |
|                             | Trauma orthopedics | 5                  | 4        | 0       |         |
|                             | Others             | 1                  | 1        | 1       |         |
| Number of pricks            | One                | 42                 | 39       | 4       | 0.619   |
|                             | More than one      | 14                 | 11       | 0       |         |
| HIV serology                | Positive           | 12                 | 2        | 1       | 0.01    |
|                             | Negative           | 43                 | 48       | 2       |         |
|                             | Unknown            | 1                  | 0        | 1       |         |

Table 2 shows characteristics of the two different study groups. Four participants crossed over. All these crossover patients were from Bed Rest to the Early Mobilization group and they were analyzed as intention to treat as the group they finally ended in.

Of the 4 participants 3(75%) were caesarian sectioned patients and females, one was a male done vascular stripping and was advised to ambulate early. All those who crossed were overweight.

As per the observed differences in the characteristics of the participants in the study, it was found out that there was no difference in the group that had bed rest and early mobilization as evidenced by the **P** value being above 0.05 which is above the level of statistical significance.

However, there was statistical difference noted between the HIV sero status of the participants in the two study groups ( $P = 0.01$ ) with more of the HIV positives being randomized to the early mobilization group compared to bed rest group. There were four cross over among the study participants, they crossed from Bed Rest to Early Mobilization group, the majority of whom were women who had caesarian section

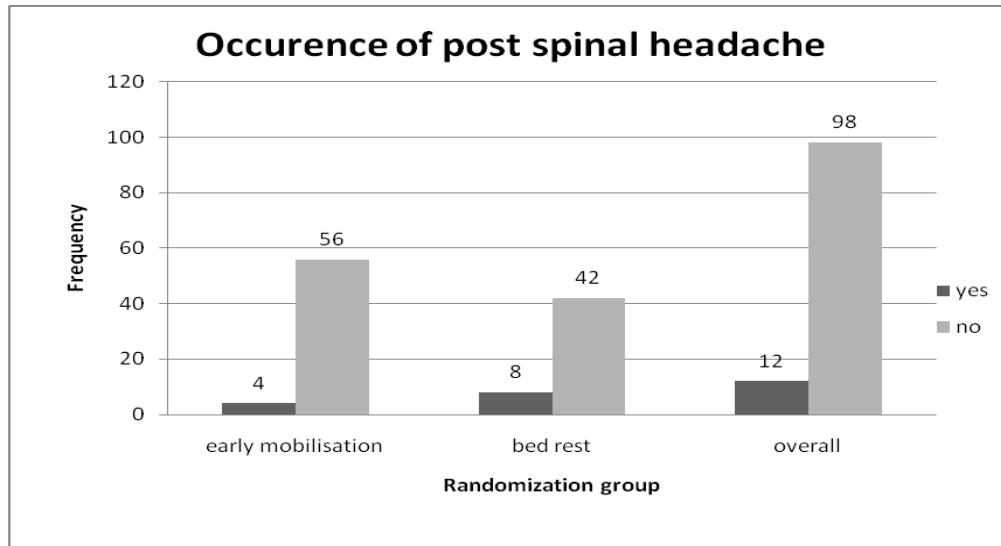
#### 4.3 OCCURRENCE OF HEADACHE FOLLOWING SPINAL ANAESTHESIA

**Table 4: Occurrence of headache in the different group**

| Time after spinal anaesthesia | Randomization group n(%)  |                 | P value |
|-------------------------------|---------------------------|-----------------|---------|
|                               | Early mobilization (N=60) | Bed rest (N=50) |         |
| 6 hours                       | 1(1.6%)                   | 2(4%)           | 0.590   |
| 12 hours                      | 3(5%)                     | 5(10%)          | 0.465   |
| 24 hours                      | 1(1.6%)                   | 5(10%)          | 0.090   |
| 48 hours                      | 1(1.6%)                   | 4(8%)           | 0.175   |
| 1 week                        | 0(0.0%)                   | 1(2%)           | 0.455   |
| Headache in all               | 4(6%)                     | 8(16%)          | 0.136   |

The participants were assessed for the headache post anaesthesia at 6 hours, 12hrs, 24 hours, 48 hours and at one week. From the table above it is noted that 4 (6%) patients from the early mobilization group developed headache which is a half the number of those in the bed rest group 8(16%) participants. Most of the cases 8 of 12(33.3%) were reported during the 12 hours post anaesthesia. There was however no statistical difference between the two groups  $P = 0.136$ .

**FIGURE 1**



The figure above shows occurrence of PDPH in the groups (4) participants in the early mobilization group developed the headache, (8) participants in the bed rest group developed headache. Overall development of PDPH was 12 participants out of 110.

#### 4.4 ASSOCIATION OF POSTDURAL PUNCTURE HEADACHE IN THE TWO GROUPS

**Table 5: Association of postdural headache in the two groups**

| Catagories                     |                       | Randomization group       |                 | P value |
|--------------------------------|-----------------------|---------------------------|-----------------|---------|
|                                |                       | Early mobilization (N=60) | Bed rest (N=50) |         |
| Age(years)                     | Less than 30          | 2(3%)                     | 3(6%)           | 0.478   |
|                                | 30-39                 | 1(1.6%)                   | 4(8%)           |         |
|                                | 40-49                 | 1(1.6%)                   | 0(0.0)          |         |
|                                | 50-59                 | 0(0.0)                    | 0(0.0)          |         |
|                                | 60 and more           | 0(0.0)                    | 1(2%)           |         |
| Gender                         | Female                | 4(6%)                     | 6(12%)          | 0.564   |
|                                | Male                  | 0(0.0)                    | 2(4%)           |         |
| Occupation                     | Formally employed     | 3(5%)                     | 3(6%)           | 0.439   |
|                                | Informally employed   | 1(1.6%)                   | 4(8%)           |         |
|                                | Unemployed            | 0(0.0)                    | 1(2%)           |         |
| Tribe                          | Bantu                 | 4(6%)                     | 7(14%)          | 0.719   |
|                                | Luo                   | 0(0.0)                    | 0(0.0)          |         |
|                                | Others                | 0(0.0)                    | 1(2%)           |         |
| BMI                            | Normal                | 0(0.0%)                   | 1(2.0%)         | 0.937   |
|                                | Overweight            | 1(1.6%)                   | 6(12.0%)        |         |
|                                | Obess                 | 3(3.0%)                   | 1(2.0%)         |         |
| Type of operation              | Laparatomy            | 0(0.0)                    | 3(6%)           | 0.568   |
|                                | Ceaserian section     | 4(6%)                     | 4(8%)           |         |
|                                | Trauma and orthopedic | 0(0.0)                    | 0(0.0)          |         |
|                                | Groin and perineal    | 0(0.0)                    | 1(2%)           |         |
|                                | Others                | 0(0.0)                    | 0(0.0)          |         |
| Operation classification       | Emergency             | 2(3%)                     | 6(3.0)          | 0.619   |
|                                | Elective              | 2(3%)                     | 2(4%)           |         |
| Number of spinal needle pricks | One                   | 3(5%)                     | 6(12%)          | 1.000   |
|                                | More than 1           | 1(1.6%)                   | 2(4%)           |         |
| HIV serology                   | Positive              | 1(1.6%)                   | 1(2%)           | 0.158   |
|                                | Negative              | 2(3%)                     | 7(14%)          |         |
|                                | Unknown               | 1(1.6%)                   | 0(0.0)          |         |

Table 4 shows association of postdural puncture headache in the two study groups. Participants of age 39 years and below were the most affected (3 in the early mobilization group and 7 in the bed rest group) though there was no statistical significance **P = 0.478**.

There was no significance of HIV status in association of postdural puncture headache in both groups  $P = 0.158$  though 1 participant in the early mobilization group was HIV positive, 2 participants were HIV negative, 1 participant had unknown serostatus compared to 7 participants who were HIV negative, 1 HIV positive in the bed rest group.

There was no statistical significance between the number of needle prick attempts in association of postdural puncture headache in the study groups **P = 1.00**. Indication of surgery and type of operation whether emergency or elective had no association with postdural puncture headache **P = 0.619** and **P = 0.568** respectively.

## **CHAPTER FIVE:**

### **DISCUSSION**

Postdural puncture headache is not very common but if it happens it can be severe that it prolongs hospital stay. Advising patients to remain in a supine position for more than twelve hours can be very uncomfortable. Though this supine position has traditionally been thought to reduce the headache once it has occurred, its efficacy is not known whether it could also prevent it. That was the basis of this study to establish whether there were any benefits to such practices.

### **5.1 DEMOGRAPHIC CHARACTERISTICS**

The age distribution in this study group indicates majority of the participants were in the age bracket of (30-39 yrs) 45.5%. The least age group of the participants was (50-59 yrs) 1.8%. Previous studies by Lybecker showed the same distribution. The reason for such distribution in this study may be partly because most of the participants were obstetric mothers who fall in that age group; The same reason could explain the smaller number of participants in the higher age groups. We also looked at the ethnicity of our study participants where majority were Bantu (94) 5.4% being that the study setting was in the central region of Uganda this could explain the finding. No other studies that have looked into these factors to make a comparison. In this study, the female were more than the male participants 79.1% and 20.9% respectively. The study done in Romania in 2014 showed a bigger number of male participants. This could be explained by the fact that the Romanian study was a prospective. Furthermore they didn't specify the type of operations in their study. In this study caesarian sections were the most performed operations this also explains the reason to why the female participants were the majority.



### **5.1.1 ASSOCIATION BETWEEN AGE AND PDPH**

In this study the most affected age group was the under 39 years though there was no statistical significance of age as regards Postdural Puncture Headache P value 0.487 contrary to one of the previous findings from a prospective study by Lybecker which showed a significance in the age group with P value 0.0001 where PDPH occurred commonly in young adults. The same findings were reproduced in the review article in Pakistan which further pointed that the incidence of PDPH was less after the fifth decade <sup>[67]</sup>. In another study performed by Amorim, on 640 patients aged 8-65 years, the post-dural puncture headache (PDPH) was more frequent in the 31-50 year group (  $p = 0.03$ )<sup>[68]</sup>

In a prospective study carried out in Romania which included 245 patients operated under spinal anesthesia, 66 patients over 60 years were present in the study; 20 of which were found among those with PDPH (30. 3%), and only 15. 38% of the patients between 30-60 years which is contrary to the findings of Lybecker<sup>[69]</sup>.

The findings in this study may be attributed to the fact that very few of my participants were above the age of 50 year, and comorbidities causing pre spinal headache were excluded from the study. Lybecker however also had a bigger sample size of 873.

This study implies that spinal anaesthesia poses no significant difference in post spinal head ache with age irrespective of whether you mobilize early or you have bed rest provided careful selection of the patients for spinal anaesthesia is done. Thus early mobilization should even be advocated in the elderly as it also helps to protect against other ailments like venous thrombosis and orthostatic pneumonias.

### **5.1.2 ASSOCIATION BETWEEN GENDER AND PDPH**

In this study, 4 female participants from the early mobilization group developed PDPH. No male participant in this group developed PDPH. Six (6) female and 2 male participants from the bed rest group developed PDPH. This finding shows that the incidence of PDPH was more in female than the male participants. Although there was no statistical significance P value 0.654. Vandane and Dripps reported, women had twice the incidence i.e., 14% of PDPH compared with men i.e., 7%. Some suggested that this difference was because of a large number of obstetric patients in the women's group <sup>[70]</sup>.

Nevertheless even after removal of these cases women still had higher (12%) incidence compared to men (7%). Others suggested that generally lower age of female patients compared with male patients accounts for the association between PDPH and gender. Kang's study reported twice the incidence of PDPH in women (13.4%) compared with men.5.7%. This difference was not valid for smaller needle sizes according to their conclusions. In this study there was standardized needle used probably in those series there was no standardization and this can explain the differences in the findings. However a 2006 review that included 18 trials (1,917 nonpregnant females, 2,163 males) showed that the PDPH was higher in the nonpregnant females group than in the male group. Female gender is more likely to develop PDPH (29% of all female subjects, compared to only 13.8% of all male patients) ( $p=0.03$ ). It is unclear why all individuals who suffer from dura mater puncture do not develop PDPH<sup>[71]</sup>. Additionally, it is unclear why women are more susceptible to PDPH than men. In a medical experiment carried out in Brazil demonstrated that, after perforating human cadaver dura mater using dural sac model with the help of an acrylic column with a dural attachment mimicking an in vivo scenario, the liquid outflow was higher using female-derived dura mater fragments than male-derived fragments<sup>[72]</sup>. High levels of estrogen in women seemed to interfere with the tone of the cerebral vessels, probably increasing the vascular distension response to CSF hypotension. Furthermore, women seemed to process the nociceptive information differently than men, exhibiting greater sensitivity to painful stimulation, thus facilitating the central sensitization process as shown in neuro imaging studies<sup>[73]</sup> In addition to the above mentioned aspects of dura mater CSF loss, possible explanations lie in the physiological, anatomical, social, and behavioral characteristics specific to women, as well as their perception of pain.

In this study there was no statistical significance of HIV status in association with postdural puncture headache in both groups  $P = 0.158$ . Among the participants that developed headache, 1 participant in the early mobilization group was HIV positive, 2 participants were HIV negative, 1 participant had unknown serostatus. 7 participants were HIV negative, 1 HIV positive participant was in the bed rest group. These findings concur with the findings of Sergio Monterio de Almeida who carried out a study in 300 volunteers  **$P = 0.01$** .

In his study LP were undertaken for research purposes in HIV positive patients not for clinical reasons. His findings were; HIV positive participants are not more susceptible to develop PDPH than HIV negative participants. This study didn't evaluate the association between PDPH and specific HIV parameters as CD4 count, CSF HIV viral load and plasma HIV viral load probably there could have been a significant association between PDPH and those variables.

In this study there was no statistically significant difference in the development of PDPH with body mass index ( $P = 0.937$ ), similar finding was reported by Yousefshahi in his prospective study of 361 patients  $P = 0.832$ , in another study that compared women in a groups of BMI  $<30$  ( $n = 65$ ) and Group  $\geq 30$  ( $n = 60$ ) there was no significant difference in the incidence of PDPH (82% vs 80%,  $P = 0.83$ ); its intensity (severe 36% vs. 23%,  $P = 0.34$ ). However contrary to the above findings in another study by Amorim that reported that PDPH incidence was noted to be low in morbid obesity<sup>[74]</sup>.

In this study there was no significant ce in development of PDPH as regards the type of surgery whether emergency or elective  **$P = 0.619$**  no previous data from other studies to be compared to these findings.

In Lybecker's study there was no significant difference in the number of needle attempts to development of PDPH which findings are in concurrence with the findings of this study  **$P = 1.00$** . The results in this study could be attributed to the standardization of the procedure where the same needle gauge was used with the same bevel orientation. It was not clearly spelt in Lybecker's study whether the same standardization was followed.

## **5.2 CONCLUSIONS**

In this study the frequency of postdural puncture headache is lower than it was thought .There are no benefits in keeping post spinal patients in bed rest for a long time though if PDPH develops lying flat reduces this headache. All those participants who developed the headache were able to improve on paracetamol without other aggressive management like epidural blood patch.

Overall, the study found that bed rest does not prevent the onset of headaches after lumbar puncture or dural puncture, regardless of the duration of rest, or the body or head positions assumed by the patient.

## **5.3 RECOMMENDATIONS**

There is no evidence to support bed rest for preventing headache following spinal anaesthesia or lumbar puncture. The adoption of this practice against the evidence implies unnecessary hospital costs, patient discomfort (e.g. among women who give birth via a caesarean section), or even complications such as venous stasis in people with risk factors.

- Bed rest after spinal anesthesia or lumbar puncture to prevent postdural puncture headache (PDPH) should not be routinely recommended.
- Instead, people should be allowed to move freely in accordance with their ability and medical recommendations.
- Another study with bigger number of participants should be carried out in Nsambya Hospital to compare the association of PDPH and the type of surgery (elective and emergency).

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**Appendix 1: QUESTIONNAIRE**

Title: Bed rest versus early mobilization in preventing post-dural puncture headache in spinal anaesthesia a randomized controlled trial

Data Collection Form

**PART I**

**Patient Identification**

Name (Initials).....

Firm..... OP.NO.....

Group..... Serial Number (IDNO).....

Telephone No..... Address.....

Date of Operation.....

**Patient Characteristics**

Age.....

Sex 1= Female 2=Male [ ]

Occupation.....

Tribe.....

**Clinical Assessment**

**(a)Clinical History**

Indication o surgery.....

Preoperative headache; Yes [ ] No[ ]

(b)Clinical Examination

Weight (Kg)..... Height (Metres).....

BMI (Body Mass Index).....

Assessment for fitness of surgery:

Type of operation 1=emergency, 2=elective [ ]

HIV serology 1= Positive, 2= Negative [ ]

PROCEDURE OF SPINAL ANAESTHESIA

Number of needle pricks; one prick [1] more than one prick [2]

CSF leakage; yes[ ] no [ ]

HEADACHE

At six 6hrs; yes [ ] no [ ] At 12hrs; yes [ ] no [ ] At 24hrs yes [ ] no [ ] At 48hrs yes [ ] no [ ]

After one week follow up; **presence of headache** Yes [ ] no [ ]

## **Appendix II: CONSENT FORM**

**Title:** Bed rest versus early mobilization in the prevention of postdural puncture headache (PDPH) in Nsambya Hospital.

I am Dr Mwesigye Ismael Samytec of the Department of Surgery, Nsambya Hospital. I am conducting a study on PDPH

You have been identified as a possible participant in this research because your medical condition requires treatment by surgery under spinal anaesthesia.

### **Purpose of the Study**

The purpose of this study is to compare the outcome of bed rest with early mobilization. Both practices are done in different countries so we want to know the practice so that we can adopt it for use in Nsambya hospital.

### **Nature of the study**

We shall be assessing headache after the operation. Another doctor using a questionnaire will do this by asking you whether you feel headache. This will be done at 6hrs, 12hrs, 24hrs, 48hrs and one week after surgery.

### **How you will be allocated the method for operation**

The allocation of the method for operation will be done randomly. That is every participant will have an equal chance to be allocated to either of the two methods of operation. You will choose the method to be used on you by picking an envelope from a bunch of sealed envelopes in the operation theatre. This will help us not to bias your thoughts and feelings when you are answering some questions when assessing the outcome of the practice.

### **Possible complications**

In both practices headache can occur but if it occurs we shall manage it.

### **Benefits to the participant**

No benefits are attached in your participation.

### **Confidentiality**

All efforts will be made to ensure that any information obtained from you during this study is kept confidential.

**Your rights**

Please note that:

- 1. Participating in this study is voluntary and free of any charge
- 2. You are free to participate or drop out of the study at anytime
- 3. You will not be denied the necessary treatment if you drop out or do not want to be part of the study

In case of any other questions concerning the study, feel free to contact me, **Dr. Ismael Mwesigye**, SHO, Department of Surgery, Nsambya Hospital on Telephone No. **0781272225**.

I....., after considering the explanations of the study, and after having understood the contents of this consent do hereby give my informed consent to Dr Ismael Mwesigye to include me in the study as a participant.

.....

Signature/Thumb print

Date

.....

Witness: Name and Signature

Date

.....

Dr. Ismael Mwesigye

Date

## **OKUKIRIZZA OKWETABA MU KUNONYEREZA**

Amannya gange nze Dr Mwesigye Ismael nga nkolera mu kitundu ekikola ku byokulongoosa mu Ddwaliro lya Nsambya. Nkola okunonyereza ku mutwe oguluma abantu ababa bafunye okusanyalazibwako ekitundu nga bakubwa akayiso mu mugongo.

Ekigendelerwa mu kunonyereza kuno kwe kuzuula wakati wokwebaka obugazi oba okusitukirawo kirina kye kyongera mu kulumwa omutwe.

Oluvanyuma lwokukubwa akayiso mu mugongo era ng'ovudde mu sweta omusawo omulala aja kubuuzza oba owulira omutwe oguluma.

Oja kuwebwa e bbaasa omunaaba ka kaadi akanaalaga ludda ki kwonaaba. Kino kijja tuyamba okuba abeerufu nga ofuna oludda kwonaaba.

Ebintu byona ebikkwataako bijja ku kumibwa nga byakyaama, era oliwaddembe okuva mukunonyereza kuno wonna woba oyagalidde.

Ekizibu ekisubirwa okuva mukunonyereza kuno wandifuna okulumwa omutwe naye singa kinaabawo ojja kufuna obujanjabi.

## **EDDEMBE RYO MU KUNONYEREZA**

1. Oli wa ddembe okuva mukunonyereza kuno mu kiseera kyonna woba oyagalidde.
2. Okwetaba mukunonyereza si kwakusasulirwa.
3. Singa onaaba ovudde mukwetaba mukunonyereza kuno, tojja kummibwa bujanjabi bwona.

Bwoba olina kyewandyagadde okumanya osobola okunkubira ku buliwendi nkufuna ku 0781272225.

Nze ..... oluvanyuma lw'okunyonyoka ebingambidwa nzikirizza okwetaba mukunonyereza kuno nga ntegeera bulungi era sikakiddwa.

Ekinkumu, enaku zomwezi.....

Omujulizi, enaku zomwezi.....

Dr Mwesigye Ismael