

**UNIVERSITY OF GHANA**



**COLLEGE OF HEALTH SCIENCES**

**PULMONARY FUNCTIONAL CHANGES IN GHANAIAN PATIENTS UNDERGOING  
SPINAL ANAESTHESIA**

**BY**

**MELODY KWATEMAH AGYEI-FEDIELEY**

**(ID NO: 10320237)**

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## DECLARATION

I, MELODY KWATEMAH AGYEI-FEDIELEY, hereby declare that this thesis is my own work. I carried out this study at the Greater Accra Regional hospital, Ridge under the supervision of Dr. Bartholomew Dzudzor and Dr. Ebenezer Owusu Darkwa of University of Ghana Medical School, Korle-Bu. Neither I nor anyone has submitted this thesis either completely or in part for the award of any other degree in this or any other University.



Signature

(Melody Kwatemah Agyei- Fedieley)

Date: July 2019

### Principal Supervisor



Signature

Dr. Bartholomew Dzudzor

Date: July 2019

### Co-Supervisor



Signature

Dr. Ebenezer Owusu Darkwa

Date: July 2019

## **STRUCTURED ABSTRACT**

**BACKGROUND:** Although spinal Anaesthesia remains the anaesthetic technique of choice for many surgeries below the umbilicus, it may be associated with increased risk of cardiopulmonary complications such as hypotension, bradycardia and intraoperative cardiopulmonary arrest. Spinal Anaesthesia blocks autonomic, motor and sensory nerves which may affect pulmonary function. In the general population, reduction in the forced expiratory volume in one second (FEV<sub>1</sub>) is a robust predictor of sudden cardiac death in patients without primary heart or lung disease. It remains unclear how spinal Anaesthesia affects the pulmonary function of healthy individuals and how these changes impact on the incidence and/or severity of spinal Anaesthesia related intraoperative and postoperative complications.

**GENERAL AIM:** To determine pulmonary functional changes and its association with perioperative cardiopulmonary complications in patients undergoing spinal Anaesthesia for elective surgery

**MATERIALS AND METHODS:** An analytical cross-sectional study of 50 patients that meet the American Society of Anesthesiologist physical status class I or II with no history of primary heart or lung disease scheduled for elective surgery under spinal Anaesthesia were recruited for the study. Pulmonary function test (assessed by peripheral capillary oxygen saturation, spirometry and arterial blood gas) was done prior to induction of spinal Anaesthesia, 30min after induction of spinal Anaesthesia and at full recovery from spinal Anaesthesia. The changes in pulmonary function and how they predict the risk of adverse complications (hypotension, bradycardia, dysrhythmia, dyspnoea, nausea and vomiting) in the intraoperative and postoperative period were recorded. Repeated Measures ANOVA was used to determine pulmonary functional changes during spinal Anaesthesia and Logistic regression analysis was

used to study the association between baseline pulmonary function and intraoperative and postoperative complication, with adjustments for potential covariates.

**RESULTS:** Spinal Anaesthesia was associated with pulmonary functional changes. There was a significant reduction in FEV<sub>1</sub> (best and predicted) and PEF<sub>R</sub> (best and predicted) during and post recovery from spinal Anaesthesia. There was a significant reduction in P<sup>H</sup> during Anaesthesia as compared to preoperative (baseline) and post recovery. This was observed with increase in PaCO<sub>2</sub> and PaO<sub>2</sub> though Arterial blood gas values were within normal physiological limit. There was no significant association between pulmonary function indices (FEV<sub>1</sub>predicted and PEF<sub>R</sub> predicted) and spinal Anaesthesia related complications. However, their ODDS ratio determined (preoperative, intraoperative and postoperative) indicated that spinal Anaesthesia related complications were more likely to occur for a unit change in the pulmonary function.

**CONCLUSION:** Spinal Anaesthesia affects pulmonary function. This causes reduction in FEV<sub>1</sub> intraoperatively and post operatively. Reduction in FEV<sub>1</sub> may be a contributing factor to other mechanisms that result in spinal Anaesthesia related complication. Reduction in FEV<sub>1</sub> may be more likely to predict the risk of development of spinal Anaesthesia related complication.

**RECOMMENDATION:** Improved monitoring should be a mandatory safety requirement for all patients as changes in physiological parameters occur during and after spinal Anaesthesia. It is pertinent that all patients be monitored well into the postoperative phase of recovery.

## **DEDICATION**

I dedicate this thesis to Dr. Charles Hayfron-Benjamin.

Your mentorship, knowledge, excellence and determination in your field is a model to me and several others.

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I thank God my helper for his numerous investments into this work.

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## LIST OF ABBREVIATION

ABG	Arterial blood gas
ASA	American Society of Anesthesiologists
CSF	Cerebrospinal fluid
C3-C5	Third and fifth cervical vertebrae
FEV <sub>1</sub>	Forced expiratory volume in one second
FRC	Functional residual capacity
FVC	Forced vital capacity
GARH	Greater Accra Regional Hospital
K <sup>+</sup>	Potassium Ion
L2	Second lumbar vertebrae
L4- L5	Fourth and fifth Lumbar vertebrae
L3-L4	Third and fourth Lumbar vertebrae
Na <sup>+</sup>	sodium ion
PaO <sub>2</sub>	Partial pressure of arterial oxygen
PaCO <sub>2</sub>	Partial pressure of arterial carbon dioxide
PEFR	Peak expiratory flow rate

PFT	Pulmonary function test
p <sup>H</sup>	Logarithm scale of Hydrogen ion concentration
PDPH	Post-Dural puncture headache
OR	Odds ratio
SA	Spinal Anaesthesia
SaO <sub>2</sub>	Arterial oxygen saturation
S <sub>1</sub>	First Sacral vertebrae
5-HT <sub>3</sub>	5-hydroxytryptamine 3 receptors
ATP	Adenosine Triphosphate

# CHAPTER ONE

## 1.0 BACKGROUND

### 1.1 Introduction

Spinal Anaesthesia (SA) is a technique whereby local anaesthetic drugs are administered into the cerebrospinal fluid (CSF) (Abdelbarr *et al.*, 2014). It is generally indicated for surgeries below the umbilical region and ideal for several obstetric, gynaecological, genitourinary and orthopaedic procedures (Gligorijevic, 2011; Mung *et al.*, 2015). It is a simple, reliable (about 3% failure rate), and quick procedure, which gives optimal operating conditions in terms of analgesia and muscle relaxation (Siddiqi & Jafri, 2009). Additionally, it is cheaper and generally devoid of complications related to airway difficulties and pulmonary aspiration compared to general Anaesthesia (Regli *et al.*, 2006). Because of its advantages, it is better appreciated among patients, surgeons, obstetricians and anaesthetist worldwide (Regli *et al.*, 2006).

Although SA remains the anaesthetic technique of choice for many surgeries below the umbilicus, it is associated with increased risk of perioperative complications including hypotension, bradycardia, dysrhythmias, nausea and vomiting and intraoperative cardiorespiratory arrest (Arruda *et al.*, 2011; Mung *et al.*, 2015). For example, the incidence of hypotension following SA is 48% as compared to 28% in the general Anaesthesia technique (Alnour *et al.*, 2015). Common dysrhythmias during SA include bradycardia, atrioventricular block (1st and 2nd-degree heart block), and multiple ventricular ectopic beats (Shen *et al.*, 2000). The rates of these dysrhythmias have ranged from 1.2% to 6.7% and may be associated with

increased mortality (Shen *et al.*, 2000). According to a study conducted in Libya by Alnour *et al.*, (2015) 12% of patients had vomiting as side effects associated with SA as compared to 8% in general Anaesthesia. Additionally, perioperative cardiac arrest may complicate SA, with reported rates ranging from 0.2 to 1.1 per 10,000 adults and from 1.4 to 4.6 per 10,000 children undergoing SA (Andres, 2012). Though cardiorespiratory depression is rare, a review by Šoštarić & Oremuš, (2013) affirms an increase in the incidence of cardiorespiratory depression during SA. This varies from 1.3 to 18 in 10,000 patients. About 50% of these patients who experienced cardiorespiratory depression or arrest during SA were among young healthy adults many of which were undergoing minor surgeries. Over 40% of mortality rates were recorded among this group. Both the age group and health status may suggest that such complications may be avoided (Pollard, 2000).

According to the American Society of Anesthesiologists and Association of Anaesthetists of Great Britain and Ireland, the standard perioperative monitoring required for each person undergoing SA should include non-invasive blood pressure, pulse oximetry, electrocardiography and temperature (Misra *et al.*, 2016). When monitoring physiological indices adverse cardiopulmonary complications following SA could be detected and treated (Misra *et al.*, 2016). Standard vasoactive drugs like phenylephrine and ephedrine, as well as anticholinergic agents like atropine or glycopyrrolate, are beneficial in treating hypotension and bradycardia, respectively (Misra *et al.*, 2016). Intravenous infusion given before induction of SA (preloading) has been the first line of intervention in preventing and treating SA- related hypotension (Bajwa, Kulshrestha, & Jindal, 2013). Perioperative nausea and vomiting under SA are often patient-reported and often treated with a variety of drugs including 5-hydroxytryptamine (5-HT<sub>3</sub>)

receptor blockers like granisetron, ondansetron and pro-kinetic drugs like metoclopramide (Kane & Pugh, 2017).

Major risk factors for SA-related complications include advancing age, increased body mass index, gravidity, history of hypotension, baseline systolic blood pressure, baseline heart rate, fluid preloading, and the level of sensory blockade achieved at the induction of SA (Fakherpour, Ghaem, Fattahi, & Zaree, 2018). The mechanisms for these SA-related complications are not fully understood. Although sympathetic chain blockage and/or the Bezold-Jarisch reflex mediated by 5-hydroxytryptamine (5-HT<sub>3</sub>) receptors may play critical roles, not all the complications can be explained by this mechanism (Campagna & Carter, 2003; Kane & Pugh, 2017). Spinal Anaesthesia (SA) is associated with a reduction in the lung volumes such as forced expiratory volume in one second (FEV<sub>1</sub>) and forced vital capacity (FVC) (Campagna *et al.*, 2003). In the general population, reduction in FEV<sub>1</sub> has been reported to be a predictor of sudden cardiac death in patients without primary heart or lung disease (Magnussen *et al.*, 2017). Reduction in lung volumes during SA could, therefore, impact on the risk of development of cardiopulmonary complications. However, it remains unclear how pulmonary functional changes during SA affects the risk of developing adverse cardiopulmonary complications during and after surgery. Spinal Anaesthesia may also cause relaxation of some respiratory muscles and therefore affect lung function. Reduction in lung volumes in the un-anaesthetized general population predicts cardiorespiratory morbidity and mortality (Kurl *et al.*, 2015). Therefore, changes in pulmonary function during SA could explain some of these cardiopulmonary complications.

## 1.2 Problem Statement

The use of SA is well established in low to middle-income countries with about 50% of all surgical procedures done under SA (Adelin *et al.*, 2018). The Department of Anaesthesia and Critical Care, Greater Accra Regional Hospital (GARH) annual records reports 69% of all surgical cases between 2015 and 2017 were done under SA. Despite SA is a technique of choice for many surgeries, it is accompanied by sudden and serious cardiopulmonary related complications such as hypotension, bradycardia, nausea and vomiting, dysrhythmia, dyspnea and cardiopulmonary arrest which results in brain damage, increase morbidity and mortality (Kane & Pugh, 2017; Kurhekar *et al.*, 2014; Limongi & Lins, 2013; Tarkkila PJ, 1991). About twenty per cent (20%) of all cases done under spinal Anaesthesia experiences at least one of these cardiopulmonary adverse effects such as hypotension, bradycardia, dysrhythmias and nausea and vomiting, a 2017 annual statement report from Anaesthesia department, GARH. Five deaths (0.07 % of all cases) occurred under SA between 2017 and 2018 at the GARH. These mortalities were recorded intraoperatively or postoperatively and preceded sudden bradycardia, hypotension, and difficulty in breathing or seizures. These complications do not only occur in high-risk patients but also in healthy adults without primary heart or lung disease (Alegbeleye, 2018; Sharma, 2018). The concern is that it presents very suddenly (within seconds), not only immediately after induction of SA but also hours following SA which makes it difficult to detect. Additional human resources, robust equipment and medications such as intensive care (ICU) admissions, defibrillators (automated), arterial blood gas analyzers, capnography, medications (epinephrine, atropine, ondansetron, amiodarone) and continuous oxygen supply are needed for management. These are limited in many of our hospitals across the country.

### **1.3 Justification**

Cardiorespiratory adverse effects during Anaesthesia in the perioperative period are of grave concern to Anaesthesia caregivers because of the associated morbidity and mortality. Quality of life of healthy patients can be significantly impacted. Furthermore, turnover rates of daily surgical cases can be slow due to the length of time used to resuscitate a single patient. These incidences may also require expert human resources and sophisticated expensive equipment such as defibrillator which are unavailable in many hospitals in Ghana adding to potential poor outcomes.

The ability to establish an association between patients' pulmonary function and the risk and/or severity of perioperative cardiopulmonary complications following SA, may be useful in identifying apparently healthy patients with increased risk of developing cardiopulmonary complication following SA. Also, it may provide preliminary data on the patient's cardiopulmonary function prior to discharge to the ward from the theatre recovery suite. Institutional preventive strategies against SA-related complications such as modifying the technique of Anaesthesia in at-risk groups, the requirement of additional monitoring, and emergency preparedness can be further established towards improved outcomes. Ultimately, morbidity and mortality rates will be reduced. Additionally, results from this study may add to the existing knowledge on mechanisms linking spinal Anaesthesia and adverse cardiorespiratory events in patients with assumed normal cardiac function.

#### **1.4 Main Objective**

To determine pulmonary functional changes and their association with perioperative cardiopulmonary complications in patients undergoing SA for elective surgery

#### **1.5 Specific objectives**

The specific objectives for the study were to;

1. Evaluate the preoperative (baseline), intraoperative and postoperative pulmonary function in the patient scheduled for elective surgery under SA
2. Determine the incidence of intraoperative and postoperative complications (hypotension, dysrhythmias, dyspnoea and nausea and vomiting) following spinal Anaesthesia
3. Determine the association between pulmonary function and the risk of developing intraoperative and/or postoperative complications (hypotension, dysrhythmia, dyspnoea, nausea and vomiting) following SA

#### **1.6 Hypothesis**

Patients undergoing SA will demonstrate a reduction in FEV<sub>1</sub> and PaO<sub>2</sub> compared to baseline. Significant changes from baseline (FEV<sub>1</sub>) and PaO<sub>2</sub> may have a higher risk of perioperative complications following SA.

## CHAPTER TWO

### 2.0 LITERATURE REVIEW

#### 2.1 Spinal Anaesthesia

Spinal Anaesthesia (SA) refers to a technique whereby local anaesthetic is administered in the cerebrospinal fluid (CSF) (Gligorijevic, 2011; Kakkar *et al.*, 2017). Spinal Anaesthesia has become the preferred method of Anaesthesia for many surgeries even in resource limiting countries like Sierra Leone and Cote D'Ivoire today with majority (46%) surgeries done under spinal Anaesthesia because of its effective surgical Anaesthesia for surgeries below the umbilicus (Adelin *et al.*, 2018; Arzola & Wieczorek, 2011). During spinal Anaesthesia, local anaesthetic agents such as bupivacaine are introduced into the subarachnoid space to block the thoracolumbar spinal and motor nerves (Geng *et al.*, 2014). An injection is made below the level where the spinal cord ends (L2) in adults thus L3-L4, L4-L5 intervertebral spaces are preferably used. It can also be made at L5-S1 or L2-L3 interspaces (Ankorn & Chris. Casey., 2000; Ituk Unyime, 2018). The superior iliac crest (Tuffier's line) is used as a landmark (Ankorn & Chris. Casey, 2000; Gligorijevic, 2011).

Spinal Anaesthesia is generally indicated for lower abdominal surgeries such as obstetrics, gynaecological, urogenital, perineal and surgeries of the lower extremities (knee replacement surgeries, arthroscopies, and fracture repairs) (Ituk Unyime, 2018). Although spinal Anaesthesia has minimal effect on ventilator function, high spinal can significantly affect intercostal nerve and muscle function and thus predispose patients to dyspnea and reduced ability to cough (Saraswat, 2015). Contraindications to spinal Anaesthesia include inadequate resuscitation drugs

and equipment, patient refusal, severe hypovolaemia, infection at SA procedure site, septicaemia, coagulopathies, increased intracranial pressure and fixed cardiac output states like aortic stenosis and mitral stenosis (Ankorn & Chris. Casey, 2000).

## **2.2 History of spinal Anaesthesia**

A description of SA was first by a neurologist, James Leonard Corning in 1885. In his experimental study in New York City, he injected local anaesthetic cocaine into the subarachnoid space of a dog. Corning realizing the marked weakness in the hindquarters of the dog minutes after injection replicated in humans (Zundert, 2017). Reporting the milestone in regional Anaesthesia, spinal Anaesthesia is the first in clinical practice. According to Wulf (1998), the first documented to use spinal Anaesthesia in clinical practice was German surgeon, Augustus Karl Gustav Bier. He used cocaine intrathecal in 1898 on six patients for lower extremity surgery. His 'self-experiment' and that of his assistant Dr Otto Hilderbrandt, further investigated into complications associated with spinal anaesthesia such as vomiting and headache.

Many scientists acknowledging the complications associated with such a novel technique in the speciality of Anaesthesia advanced Bier's investigations and developed equipment and techniques to minimise such side effects. Notable among such investigators was Herbert Green who realised the loss of cerebrospinal fluid (CSF) was a major problem which caused post-dural puncture headache (PDPH) and developed the 26-gauge smooth-tip smaller Greene needle (Wulf, 1998). To buttress his assertion, Greene argued that 'post-dural puncture headache is caused by trauma to the spinal dura sufficient to result in excessive leakage of cerebrospinal fluid to the point at which the brain is left without a water cushion'(Wulf, 1998). In his work, out of

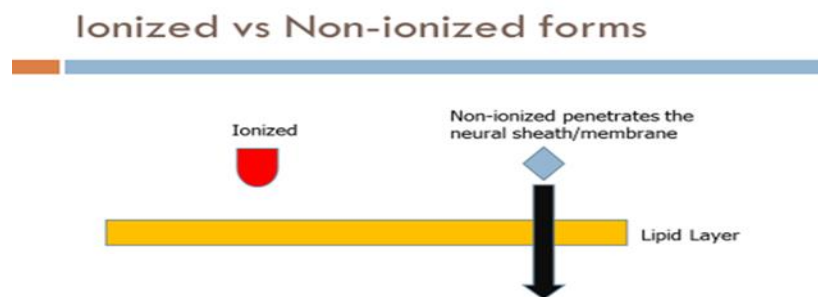
215 patients, only 0.9% developed a headache after spinal Anaesthesia with his needle. This made Greene needle popular especially in obstetrics until modifications of the Sprotte needles occurred in the 1990s to produce the needles that are in use today (Ross, Chadwick & Mancuso, 1992; Xu *et al.*, 2017).

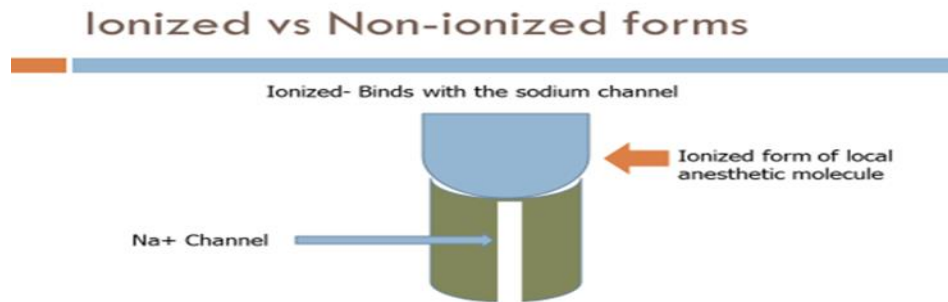
Theodore Tuffier, a French surgeon popularized spinal Anaesthesia in Europe. In his studies in 1900, he reported that cocaine should not be injected until CSF was recognized in the needle hub; a proof that one is in the subarachnoid space (Zundert, 2017). Another professor of surgery at the University of London, Arthur Barker in 1907 also worked to improve the techniques in SA. These included the use of hyperbaric spinal local anaesthetic, emphasis on sterility, and ease of midline over the paramedian Dural puncture (Hocking & Wildsmith, 2004). He also advanced in investigating a decrease in blood pressure (hypotension) after spinal Anaesthesia. Spinal Anaesthesia technique has progressed significantly from improved equipment, pharmacological agents to a greater understanding of physiology and anatomy in recent times.

### **2.3 Physiology of spinal Anaesthesia**

In the nerve cell, the resting membrane potential is maintained by the concentration gradients of two major ions, sodium ( $\text{Na}^+$ ) and potassium ( $\text{K}^+$ ). The relative membrane permeability of the nerve cell to these ions is maintained by the  $\text{Na}^+/\text{K}^+$  Adenosine Triphosphate (ATP) pump (Lodish, Berk, Zipursky, 2000). When nerve fibres in the subarachnoid space are stimulated, they transmit electrical impulses in a form of sensation. This is achieved by the movement of  $\text{Na}^+$  across the cell membrane into the cell making it less electronegative (depolarization) and generating an action potential (Mcleod, 2017).

Local anaesthetic inhibits depolarization of the nerve membrane by interrupting both  $\text{Na}^+$  and  $\text{K}^+$  currents (Bianconi, 1998; Robyn Gmyrek, 2015). This prevents the nerve cell from achieving threshold potential and therefore no action potential is attained. According to Robyn Gmyrek (2015), regarding the binding effect of local anaesthetic, the Specific receptor theory was propounded. In this theory, local anaesthetic moves across the cell membrane and reversibly binds to a specific sodium ion receptor at the opening of the voltage-gated sodium channel. Local anaesthetic contains a lipophilic aromatic portion, which is made of a benzene ring. This is in the non-ionized form and therefore diffuses easily through the highly lipophilic nerve cell membrane (McLeod, 2017). When neurons are stimulated, it further increases the local anaesthetic affinity to the voltage-gated  $\text{Na}^+$  channel. This binding effect of local anaesthetics alters the structure or function of the channel and inhibits sodium ion movement.





**Figure 2. 1: Mechanism of Local anaesthetic molecule**

**Source: adapted from (Moos, 2018)**

Conduction of impulses along all nerves with which local anaesthetic comes in contact in the subarachnoid space are blocked, although some nerves are easily blocked than others. The motor nerves convey messages for muscles to contract and when they are blocked, muscle weakness results (efferent impulses). Sensory nerves transmit sensations such as touch and pain to the spinal cord and from there to the brain (afferent impulses). Autonomic nerves control the calibre of blood vessels, heart rate, gut contraction, and other functions not under conscious control (efferent impulses). Small myelinated fibres get blocked quickly than larger unmyelinated fibres. (Mumba & Kasandji, 2017).

With SA block, there is a difference between sympathetic, sensory, and motor block level. The dermatome is an anatomical configuration to denote the level of sensory block (abolishment of sensation) on the skin. The sensory level is two to six dermatome levels lower than the sympathetic level and approximately two dermatome levels higher than the motor level (Hocking, 2006; Ituk Unyime, 2018) For instance, a sensory block at T4 could lead in a

sympathetic block from T1-T4 which will affect the cardio accelerator fibres and result in bradycardia (Arruda *et al.*, 2011; Šoštarić & Oremuš, 2013). The modified Bromage score is used for the assessment of motor block (blockade of movement)(Graham Hocking, 2006). A study by Geng *et al.*, (2014), illustrates a Bromage score of zero [0] indicates no motor paralysis, a score of one [1]: inability to raise an extended leg, but able to move knee and foot. A score of two [2] indicates an inability to raise an extended leg or to move the knee, but able to move the foot and score three [3] indicates an inability to raise an extended leg or to move knee and foot. Autonomic fibres (type B, myelinated and moderate size) are blocked first followed by sensory pain (type C, small unmyelinated) fibres and motor fibres (Type A, large) last (G Hocking & Wildsmith, 2004; Robyn Gmyrek, 2015).

## **2.4 Effects of spinal Anaesthesia**

The physiologic effects of SA depend on the speed of onset of the block and patient factors. This manifest as a result of the blockade of sympathetic, motor and sensory nerves, the compensatory reflexes, and unopposed parasympathetic tone (Ituk Unyime, 2018).

### **2.4.1 Cardiovascular effect**

Nerve fibres that affect the vasomotor tone of the arterial and venous vessels arise from T5-L1(Gligorijevic, 2011). This is generally within the area the anaesthetist seeks to block during spinal Anaesthesia technique as a result, there is a decrease in the following measured parameters; mean arterial pressure 21%, stroke volume 25%, cardiac output 17%, total

peripheral resistance 5% and a corresponding increase in heart rate by 3.7 % immediate following spinal Anaesthesia in healthy adults without cardiac and pulmonary diseases and reduced heart rate where the cardioaccelerator fibres are involved (Salvatore *et al.*, 1952; Ward *et al.*, 1965). In furtherance, Gligorijevic (2011), in his studies showed that there is a decrease in blood pressure (33% incidence of hypotension in non-obstetric populations), decrease in heart rate (13% incidence of bradycardia in non-obstetric populations) and also in cardiac contractility following spinal Anaesthesia. Additionally, in an age comparative study by Laire, *et al.*, (2015) on the cardiovascular effect of low dose spinal Anaesthesia observed that, whereas patients under age 70 years group experienced no hypotension, 66% of patients older than age 70 experienced hypotension with a median time to first hypotensive episode within 20-min post-SA. In a similar observational study done by Pusapati, Sivashanmugam, & Ravishankar, (2010), for forty-one ASA I and II patients undergoing SA for elective gynaecological laparoscopy confirms a reduction in mean heart rate and arterial blood pressure by 20% as compared to their preoperative vital parameters. Another prospective study conducted on 511 participants, who underwent spinal Anaesthesia for caesarean section had an incidence of hypotension as mild (20%) moderate (35%) and severe (40%). It was further found out that a sensory block higher than T4 was associated with a higher risk of hypotension (Fakherpour, Ghaem, Fattahi, & Zaree, 2018).

#### **2.4.2 Respiratory effect**

The diaphragm is the major muscle involved in quiet respiration and it is innervated by the phrenic nerve (C3-C5). This may be hard to block during SA. However, functions of intercostal

and abdominal muscles that aid in respiration may be reduced by SA as well as the efficacy of coughing and sneezing since the intercostal nerves are interrupted (Ostrowska & de Carvalho, 2015). The physiologic effect on lung function is determined by the extent of motor blockade. A decrease in vital capacity with spinal Anaesthesia has been described as 3%. A change in vital capacity is noticed by the patient if it is 10% or more (Magnusson, 2010). Similarly, Ostrowska and de Carvalho (2015), in their study of the thoracic sympathetic trunk revealed that indeed, forced vital capacity in the first second and forced expiratory flow rate was observed to be reduced in asymptomatic patients with thoracic sympathectomy. Additionally, SA decreased forced vital capacity (FVC), Forced expiratory volume during the first second (FEV<sub>1</sub>) and Peak expiratory flow rate (PEFR) (Geng *et al.*, 2014).

Further significant decrease in pulmonary changes after SA in mean parameters such as forced expiratory flow in the mid-region of 25% point and 75% point of forced vital capacity (FEF<sub>25%-75%</sub>), FVC, FEV<sub>1</sub> and PEF has been observed in other studies not only immediately after SA but persisted into the recovery period even when sensory block had worn off (Kelly, & Fitzpatrick, 1996). These changes may have an effect on the (blood gas) changes in the respiratory system at the tissue level. A study by Ward *et al.*, (1965) on the respiratory effect of SA revealed an increase in mean difference in partial pressure of oxygen (PaO<sub>2</sub>) by 14.9mmHg from baseline and a mean decrease in difference in partial pressure of carbon dioxide (PaCO<sub>2</sub>) by 6.5mmHg from baseline following SA. It was also observed that the hydrogen ion concentration (pH) of blood had a mean increase of 0.05 mmHg from baseline values. This increase in PaO<sub>2</sub> they attributed to hyperventilation due to apprehension observed in the patients (Ward *et al.*, 1965).

### 2.4.3 Gastrointestinal effect

The inhibition of sympathetic tone (T6- L2) causes a relative increase in parasympathetic control. Also, the addition of vasoconstrictors to local anaesthetic increased the incidence of nausea and vomiting during SA (Alain Borgeat,& Georgios Ekatodramis, 2003). Several mechanisms have been postulated to play a role in causing postoperative nausea and vomiting during spinal Anaesthesia. Reviews from retrospective analytic studies have found that hypotension may lead to ischaemia of the brain stem which is known to activate the circulatory, respiratory and vomiting centres grouped together in the medulla (Alain & Georgios, 2003). Other investigators suggest the resultant hypotension from SA leads to gut ischaemia and release of emetogenic substances such as serotonin from the intestines. In a randomized trial, patients were observed to experience nausea and vomiting as side effects of SA between 15% and 35% respectively in the antiemetic and control group respectively (Spelina & Gerber, 1984). According to a study conducted in Libya by Alnour *et al* ( 2015), 12% of patients had vomiting as side effects associated with spinal Anaesthesia as compared to 8% in general Anaesthesia.

Other effects of spinal Anaesthesia include post-spinal shivering. A sensory block to T4 may cause severe interruption of the cardio accelerator fibres which interfere with sympathetic vasoconstriction. The vasodilative effect causes a redistribution of heat towards the periphery. This may cause shivering due to the change in core temperature, increase oxygen consumption and lead to hypoxaemia (Shawana Javed *et al.*, 2011). A study on prevention of shivering during regional Anaesthesia reports the incidence of 55% occurrence in the placebo group (Abdelrahman, 2012). In a prospective study at a sub-Saharan hospital on the prevalence of post

spinal shivering, it was observed that 8.5% experienced shivering. This occurred mostly within the 20min from induction of spinal Anaesthesia (Luggya *et al.*, 2016)

## **2.50 Assessment of Pulmonary Function**

Respiratory function is determined primarily by the pulmonary function test. It is an objective and standardized measurements used for assessing the presence and severity of respiratory dysfunction (Sharma., 2018). Pulmonary function testing (PFT) comprises of spirometry, lung volume measurements (helium dilution, nitrogen washout, body plethysmography) and tests that evaluate the gas exchange function of the lung (pulse oximetry, diffusion capacity of carbon monoxide and arterial blood gases) (McCormack, 2018; Sewa & Ong, 2014).

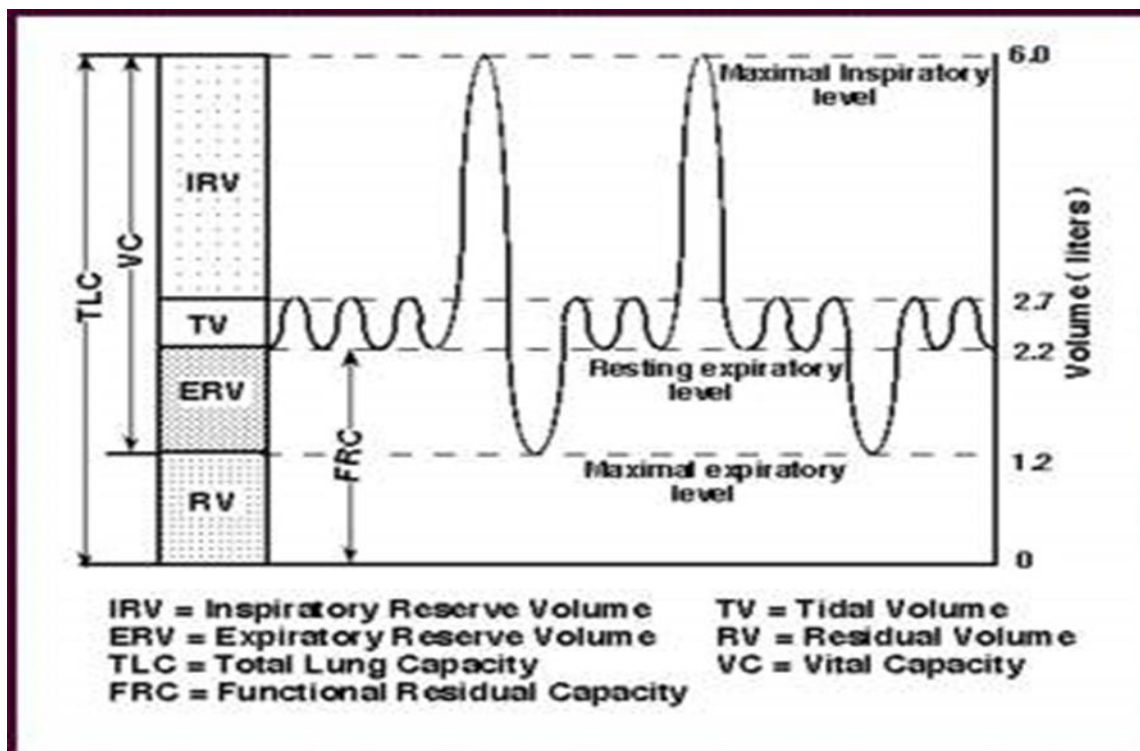
According to Sewa & Ong (2014), the goal of PFT is to predict the presence of pulmonary dysfunction, identify patients at perioperative risk of pulmonary complications, to know the functional nature of the disease (obstructive or restrictive) and assess the severity of the disease. It also identifies patients at increased risk of morbidity and mortality, weans the patient from the ventilator in intensive care unit and medicolegal- to assess lung impairment as a result of occupational hazard and Epidemiological surveys (Sewa & Ong, 2014).

### **2.5.1 Lung volumes and capacities**

Pulmonary function test tracing has four lung volumes and five capacities. The addition of 2 or more volumes comprises a capacity. The respiratory system is said to be at equilibrium after

expiration where there is no respiratory effort (rest). The chest wall and the lungs achieve equal and opposing forces at a steady state volume called functional residual capacity FRC (2.4L) (Sharma., 2018).

During quiet breathing, the inspiratory muscles contract (diaphragm and external intercostal). Lung volume increases and air flows into the lungs due to changes in pressure gradient and during expiration, inspiratory muscles simply relax (passive) lung volume decreases to FRC and changes in pressure gradient causes air to flow out of the lungs. The volume of air that flows in or out of the lungs during quiet breathing is tidal volume (TV) which is about 0.5L -0.6L (Openstax, 2016). The volume of air added after normal breathing is Inspiratory reserve volume (IRV), about 3L in adults. Also with extra effort, the volume of air taken out of the lungs during forced expiration is expiratory reserve volume (ERV), 1.2L ( Sharma., 2018). The volume of air left in the lung under physiological conditions in the respiratory system after the extra effort on expiration is called Residual Volume (RV), 1.2L.



**Figure 2. 2: Lung volume parameters (McCormack, 2018)**

After maximum inspiration, the maximum volume of air that is expired is called Vital capacity (VC). This is composed of three (3) volumes; IRV, TV and ERV (Openstax, 2016). The total volume in the lung after maximum inspiration is total lung capacity, TLC (IRV+ TV+ ERV+ RV), 6L. The maximum volume of air one can inspire from the end-expiratory level is the inspiratory capacity (IC), (TV+IRV) approximately 3.5L (McCormack, 2018; Openstax, 2016). The spirometer is an instrument that can be used to measure these lung volume parameters.

### **2.5.2 Spirometry and pulmonary function changes**

Spirometry is a physiological test that measures lung volumes in relation to time (McCormack, 2018). It assesses the integrated mechanical function of the lung, chest wall, and respiratory

muscles by measuring the respiratory volume changes from maximal inspiration to maximal expiration thus calculate from residual volume (RV) to total lung capacity (TLC). Spirometry does not directly measure residual volume and functional residual capacity [FRC]. It is also, a noninvasive screening test of general respiratory health ( Sharma., 2018). The main parameters of spirometry are forced vital capacity (FVC) and forced expiratory reserved volume (FEV) (McCormack, 2018; Sharma., 2018).

The main indications for a spirometry test are to show the presence or absence of lung dysfunctions (baseline lung function), assess the severity of known lung disease, assess the change of lung function with time or treatment and assess the potential effect of occupational or environmental exposure (Mehrparvar, 2014; Sharma., 2018). Similarly, it is used to assess the potential risk for surgical interventions that can affect lung function and disability (Sharma., 2018). A study conducted by Magnussen *et al.*, (2017), at Gutenberg in Germany, showed that reduction in lung function parameters FEV<sub>1</sub> and FVC are related to all-cause mortality in individuals from the general population independent of their cardiac function. Furthermore, reduced lung function is a predictor for sudden cardiac death in the middle-aged non-cardiac and non-respiratory disease population (Kurl *et al.*, 2015). Forced expiratory volume in one second and FVC may, therefore, be significant for risk stratification in sudden cardiac death among the general population (Kurl *et al.*, 2015). The ratio of FEV<sub>1</sub>/FVC distinguishes obstructive airway disease and restrictive disease. A reduced ratio is suggestive of obstructive airway disease. In instances where lung volumes are reduced, reduction in FVC in combination with a normal or increased ratio suggests restrictive disease (McCormack, 2018).

### **2.5.3 Arterial blood gases**

Arterial blood gases (ABG), is a clinical test that involves the measurement of pH of arterial blood and the amount of oxygen and carbon dioxide transported in arterial blood. It is the gold standard assessment of the severity of gas exchange impairment in patients who have low oxygen saturation (<92%) (McCormack, 2018). It reflects an effective gaseous exchange in the lungs (Wagner, 2015). It indicates two related physiological functions: pulmonary gas exchange and acid-base homeostasis. As an addition to PFT, the role of its measurement is to confirm hypercapnia, elevated bicarbonate level and/or chronic hypoxaemia in patients with a clinical history of respiratory muscle weakness (McCormack, 2018).

### **2.5.4 Arterial blood gas recommended values**

The ABG analysis measures the following components ( $P^H$ ,  $PaCO_2$ ,  $PaO_2$ , and  $SaO_2$ ) and calculates the bicarbonate ( $HCO_3^-$ ), their acceptable values and clinical significance. The hydrogen ion concentration ( $P^H$ ) has a normal range (7.35-7.45). The pH shows the presence of acidaemia or alkalaemia. A Low  $P^H$  is indicative of a higher concentration of hydrogen ions (acidosis) while a high pH indicates a lower concentration of hydrogen ions (alkalosis) (Cowley & Owen, 2013).

The  $PaCO_2$  level is the respiratory component of the ABG. It is a measurement of carbon dioxide ( $CO_2$ ) transported in the blood and is affected by  $CO_2$  removal in the lungs with a range of 35-45 mmHg. A higher  $PaCO_2$  level indicates acidosis while a lower  $PaCO_2$  level indicates alkalaemia.

Another component is the bicarbonate ( $\text{HCO}_3^-$ ) content of the blood. This is affected by renal production of bicarbonate. The normal range is 22-26 mEq/L. A lower  $\text{HCO}_3^-$  level indicates acidosis while a higher  $\text{HCO}_3^-$  level indicates alkalosis. The  $\text{PaO}_2$  normal value (75- 100mmhg) and the calculated arterial oxygen saturation ( $\text{SaO}_2$ ) (95- 100%) determines the number of haemoglobin binding sites that has oxygen bound to them which analyzes for oxygenation. A lower  $\text{PaO}_2$  or  $\text{SaO}_2$  indicates hypoxaemia (Keenaghan., 2019; Yap *et al.*, 2011).

In sixty (60) patients with restrictive lung disease where lung functions, gas exchange, and breathing patterns were studied, low values of FVC was associated with increased respiratory rate and lower tidal volumes. This mechanism maintained eucapnoea and oxygen consumption was relatively constant despite functional impairment (Javaheri & Sicilian, 1992). The body physiologically goes through a compensatory process by increasing ventilation. The increase in ventilation raises the ventilation/perfusion ratio and improves the arterial partial pressure of oxygen  $\text{PaCO}_2$ (Wagner, 2015). Hyperventilation reduces  $\text{PaCO}_2$  which increases oxygen binding in the lungs (Bohr effect) (Keenaghan., 2019; Wagner, 2015).

## **2.6 Pulmonary function changes and cardiopulmonary related complications**

Reduced lung function has been shown to be a predictor for cardiovascular diseases. A prospective cohort study was done by Truelsen, Prescott, Lange, and Boysen,( 2001) revealed that reduction in percentage predicted value of  $\text{FEV}_1$  by 10% is a predictor of first-time stroke and fatal stroke independent of patients smoking status. In similar studies where cardiovascular events ( coronary heart disease, stroke and heart failure ) were studied among young adults with a mean age of twenty-five (25) years, showed that reduced lung function is associated with

greater risk of cardiovascular events independent of sex, body mass index, blood pressure or total cholesterol (Jacobs *et al.*, 2018). Additionally, using FEV<sub>1</sub>, FVC and FEV<sub>1</sub> and FVC ratio as indicators of impaired pulmonary function, sudden cardiac death which occurred among population of middle-aged men (42-60years) without pulmonary diseases (asthma, COPD, lung cancer) in Kuopio, Finland was associated with reduction in lung function (Kurl *et al.*, 2015). This is in contrast to a retrospective cross-sectional study on the relationship between FEV<sub>1</sub> and cardiovascular risk among a population of healthy Korean adults from age eighteen without airflow limitations. Results from this indicated that FEV<sub>1</sub> has no relationship with cardiovascular risk and may not be a sensitive predictor to cardiovascular complication in the population without airway diseases (Lee *et al.*, 2011).

Changes in the hydrogen ion concentration have been found to have an effect on the cardiovascular and pulmonary functions. (Mitchell *et al.*, 1972) observed that a transient change in the P<sup>H</sup> of between 7.2 and 7.3 could result in myocardial depression in the absence of sympathoadrenal stimulation. This results in a decrease in the rate and contractility of the heart. Similarly, in a determination of potential risk factors for supraventricular arrhythmias (dysrhythmias) post lung resection, pulmonary function test was evaluated in 160 patients in a retrospective study. Though FEV<sub>1</sub> and FVC were not predictive of supraventricular arrhythmias in their study, patients with lower mean preoperative PaO<sub>2</sub> and PaCO<sub>2</sub> values as 80.8 vs. 85mmHg(p=.004) and 35.5 vs 38mmHg (p=0.01) respectively developed supraventricular arrhythmias. (Ciriaco *et al.*, 2000) in their observation, made a conclusion that low PaO<sub>2</sub> and PaCO<sub>2</sub> increased the risk of postoperative supraventricular arrhythmias. On the contrary, in a 5 year prospective study to investigate the relationship between FEV<sub>1</sub> and the risk of first episode

of atrial fibrillation among the population of 13,430 subjects in Copenhagen, Denmark aged 20 years and above researchers found out that there was an association between FEV<sub>1</sub> categorized as 60-80% predicted and the development of new episodes of atrial fibrillation. It was concluded that FEV<sub>1</sub> percentage predicted is an independent predictor of a new episode of atrial fibrillation (Buch *et al.*, 2003).

## **2.7 Pulmonary functional changes and spinal Anaesthesia related complication**

Although pulmonary functional changes in spinal Anaesthesia and related complications have not been extensively studied, there have been assertions made that spinal Anaesthesia affects respiratory muscle function. There are many variations in view as to whether this affects pulmonary function. In an observational study of forty-two patients who had gynaecological laparoscopy surgery done under spinal Anaesthesia with a sensory block at T4-T5, it was shown that there were respiratory changes with mean PaCO<sub>2</sub> increasing after 20min post spinal by 5mmHg from baseline and mean tidal volume decreasing from baseline of 355ml to 340ml 30min post-SA. It was concluded that these changes were within normal physiological limit because inspiratory diaphragmatic muscles were not affected (Pusapati, Sivashanmugam, & Ravishankar, 2010). Similarly, previous studies on changes in respiratory pattern and arterial blood gases in spinal Anaesthesia publicized a decrease in PaO<sub>2</sub> (83.1mmhg) from baseline. This was a randomized placebo-controlled study conducted among forty (40) ASA physical status I and II patients scheduled for surgery (Yamakage, Kamada, Toriyabe, Honma, 1999).

## **CHAPTER THREE**

### **3.0 MATERIALS AND METHODS**

#### **3.1 Ethical approval**

Ethical approval was obtained from the Ethical and Protocol Review Committee of the University of Ghana College of Health Sciences and the Greater Accra Regional Hospital (GARH), Ridge. Furthermore, the study was conducted in conformity with the Helsinki Declaration on Human Experimentation, 1964 with subsequent revisions (World Medical Association, 2013). Only persons meeting the eligibility criteria were recruited for the study. Study participants were adequately informed of the purpose, nature, procedures and potential risks of the study. Points emphasized included anonymity, confidentiality and the freedom to decline to participate or withdraw from the study at any time without penalty. Refusal to participate was not going to affect their clinical management in any way. Written informed consent was obtained from each person included in the study.

#### **3.2 Study site and Design**

Analytical cross-sectional study design was used for this study. The study was conducted at the Greater Accra Regional hospital (GARH), Ridge. The GARH is the only regional hospital in Greater Accra. It has a bed capacity of 500 and twelve (12) theatres. The GARH is a referral as well as a teaching hospital and has specialists where neurosurgeries, orthopaedic, ophthalmic, obstetrics and gynaecological, urogenital, laparoscopic and general surgeries are performed on 24-hour schedules. Out of an average of about 3500 surgeries performed annually, 69% are done

under SA. These cases include obstetric and gynaecological surgeries, lower limb surgeries, perineal and genitourinary as well as general surgeries below the umbilicus.

### **3.3 Study population**

The study population involved were Ghanaian patients scheduled for elective surgery under SA at the GARH. The study was restricted to Ghanaians to cater for the ethnic differences in the normative values of pulmonary functional indices (Quanjer *et al.*, 2012). Ethnic groups are located geographically and therefore could be genetically different. Ghanaian nativity was also determined by verifying the genealogy of the participant up to the third generation (great grandparents). This was assessed via a nativity questionnaire (Appendix IV). The tribes for the study were classified into eight ethnic groups. Classification of the tribes into eight ethnic groups was based on the classification by the Ghana Statistical Service and Ghana Health Service (Demographic and health survey) (Ghana Statistical Service, 2015)

### **3.4 Inclusion criteria**

1. Patients aged 18 to 59 years inclusive (as at their last birthday)
2. American Society of Anesthesiologist (ASA) physical status classification I and II
3. Patients Scheduled for elective surgery under SA

### **3.5 Exclusion criteria**

1. Patients with heart and lung diseases (self-reported and/or as per clinical records)
2. Sickle cell disease patients (as per haemoglobin electrophoresis)
3. Morbid obesity (body mass index  $> 40\text{kg/m}^2$ )
4. Patients with a previous history of Myocardial infarction (self-reported and/or as per clinical records)
5. Pregnant patients (self-reported and/or urine pregnancy test/ultrasound scan)
6. Patients who had spinal blocks using intervertebral spaces other than L4/L5
7. Patients with intraabdominal masses above the level of the umbilicus (as per clinical examination or records)
8. Patients with cognitive and hearing impairment.
9. Patients with recent oral, ophthalmic, nasopharyngeal, thoracic or abdominal surgery.

Patients went through a pre-anaesthetic assessment where thorough history was taken, all laboratory investigations were reviewed and physical examination was done. Further investigations such as chest X-ray, ultrasound, CT scan and Echo was requested for patients with above-suspected morbidities to diagnose and exclude such patients in the study.

### **3.6 Sample size determination**

The primary outcome of this study was a change of FEV<sub>1</sub> measured at baseline, and following induction of spinal Anaesthesia in the same patient. A study by Geng et al.,(2014) showed the mean baseline FEV<sub>1</sub> of 250ml while the mean change over time after baseline measurement was 230ml. Assuming the mean baseline ( $\mu$ ) of FEV<sub>1</sub> in this study is 250ml (SD = 40ml) while the

change over time( $\mu_2$ ) is 230mls and the power of the study is 80% at 95% confidence level, the size is calculated using the paired sample size formula:

$$n = \frac{(Z_{\alpha/2} + Z_{\beta})^2 \times (\sigma_d)^2}{(\mu_1 - \mu_2)^2}$$

Where

- $\sigma_d$  = standard deviation of the pair difference = 40ml
- $\mu_1$  is the mean baseline FEV<sub>1</sub> measurement = 250ml
- $\mu_2$  is the mean change of FEV<sub>1</sub> over time = 230ml
- $(\mu_1 - \mu_2)$  is the clinically meaningful difference = 20ml
- $Z_{\alpha/2}$  is the value on the standard normal distribution at 95% confidence level = 1.96
- $Z_{\beta}$  is the value on the standard normal distribution at 80% power = 0.84

$$n = \frac{(1.96 + 0.84)^2 \times 40^2}{(250-230)^2}$$

$$n = 32.32 \approx 33 \text{ participants.}$$

- Considering a drop-out rate of 10%, the sample size for the study will be 37.
- **Null hypothesis:** There will be no difference in FEV<sub>1</sub> following induction of spinal Anaesthesia

### **3.8 Sampling**

Patients who met the inclusion criteria and gave informed consent were randomly sampled and included in the study. Patients were made to pick preprinted sheets within sealed, opaque envelopes that had been sorted using computer-generated random allocation. This was done daily as per the booked number of cases scheduled for elective surgery under spinal Anaesthesia technique. Averagely two (2) patients were randomly sampled per day for three days in a week for the study.

### **3.9 Study procedures**

Patients for elective surgery were seen at the pre-anaesthetic clinic for comprehensive evaluation using a structured questionnaire (Appendix III). After clearance for surgery, informed consent was sought from the patient. Patients recruited for the study fasted as per ASA fasting guidelines (ASA, 2017).

In the pre-operative theatre suite, intravenous access was obtained with a gauge 18 cannula inserted, preferably, in the dominant hand for the administration of intravenous fluids and drugs. All subjects were given 1 litre of Lactated Ringer solution over 30 minutes immediately before the institution of spinal Anaesthesia.

Allen's test was performed to assess adequate collateral arterial circulation in the non-dominant hand. The radial artery in the non-dominant hand was located and EMLA cream 5 % (lidocaine plus prilocaine) was applied and airtight adhesive applied for one hour to provide topical anaesthetic on that hand. This site was used for radial artery cannulation for blood sampling for

ABG analysis. Patency of the radial artery was maintained with heparinized saline under pressure.

Before the induction of SA, a baseline pulmonary function test consisting of spirometry, arterial blood gases and pulse oximetry were done in all participants.

### **3.9.1 Arterial blood gas measurement**

One millilitre (1ml) of arterial blood was collected from the radial arterial cannula using a 1ml heparinized airtight syringe. Blood gas samples were placed on ice and analyzed immediately using an automated analyzer (pHOx Ultra, Nova Biomedical). Variables that were measured directly included arterial pH, arterial oxygen partial pressure ( $\text{PaO}_2$ ), arterial oxygen saturation ( $\text{SaO}_2$ ) and arterial carbon dioxide partial pressure ( $\text{PaCO}_2$ ). The automated analyzer works on these principles:  $\text{P}^{\text{H}}$ ,  $\text{PaO}_2$  and  $\text{PaCO}_2$  are respectively measured by the  $\text{P}^{\text{H}}$  (Sanz) electrode, the oxygen (Clark) electrode and the carbon dioxide (Severinghaus) electrode. Arterial bicarbonate ( $\text{HCO}_3^-$ ) was calculated using Henderson-Hassel Bach's equation. The haemoglobin-oxygen saturation was calculated using a complicated nomogram (using the haemoglobin-oxygen dissociation curve and assumes a normal P50) relating  $\text{PaO}_2$  and temperature. The actual bicarbonate, standard bicarbonate, and base excess were determined from the  $\text{P}^{\text{H}}$  and  $\text{pCO}_2$  using the Siggard-Anderson nomogram. Each electrode is calibrated at two reference points in the typical operating range according to the acceptable standards (Trulock E.P., 1990).

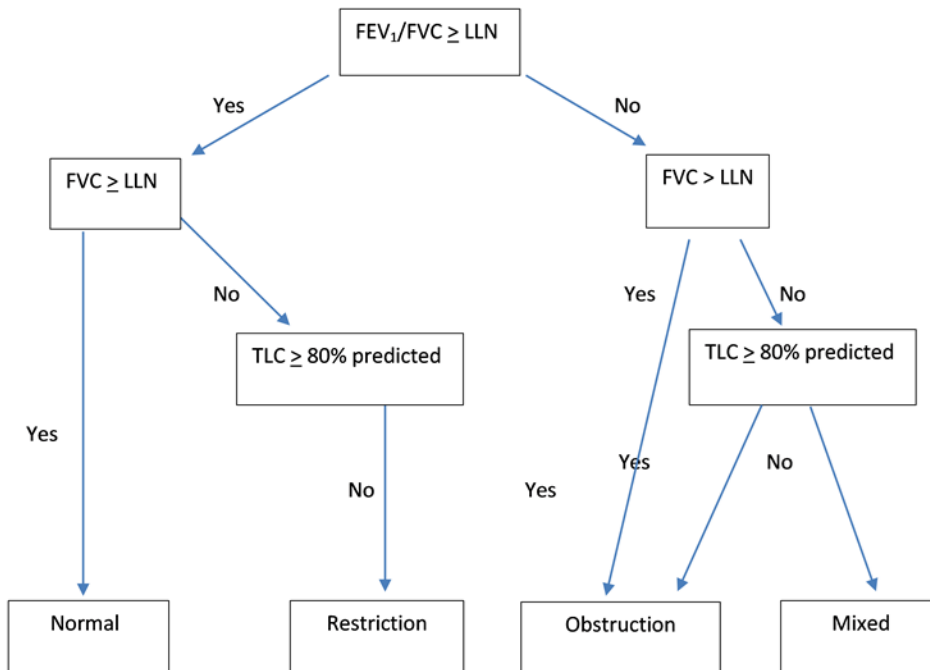
### **3.9.2 Pulse oximetry**

Peripheral capillary oxygen saturation (SpO<sub>2</sub>) and pulse rate were measured continuously throughout the surgical procedure with the Carescape Monitor B650 GE, Finland using finger probes. According to the World Health Organization (WHO) guidelines (World Health Organization, 2011), the pulse oximeter works using the light emitting diodes (LEDs) and a photo-detector. Light is emitted from one side of the probe through the tissues of the finger to the other side of the probe. Some of these lights emitted is absorbed by the blood and tissues. As blood pulsates through the tissues, the photodetector senses it and the microprocessor then calculate the value of the oxygen saturation (SPO<sub>2</sub>).

### **3.9.3 Spirometry**

Three measurements (baseline, intraoperative[30minutes after spinal induction] and post-operative) Spirometry testing in the participants was conducted using the electronic Morgan ComPAC spirometry software (version1.10, USA ) by a trained technician in accordance with the American Thoracic Society/ European Respiratory Society (ATS/ERS) guidelines (Sewa & Ong, 2014). This was calibrated each day with a 3L syringe before testing in accordance with the manufacturer's instructions. The correct usage of the device, the position of mouthpiece and nose clip was demonstrated to participants prior to the test. The participant was asked to place the mouthpiece in his/her mouth and nostrils closed with a nose clip so that he/she breaths only through the mouth. Participants performed spirometry test in the supine position with a 30-degree head elevation. The participant was asked to take five normal tidal breaths through the mouthpiece. After the fifth tidal breath, the participant was asked to inspire as much air as they possibly can, then expire as much air as quickly and forcibly as possible. Spirometry was done at

least three times per each assessment and the best measurement was taken (to obtain technically acceptable and reproducible results) after a 3 to 5 minutes rest interval between tests. Based on the participant's age, gender, height, and ethnic group using the Global Lung Initiative 2012 equations predicted values of spirometry indices was determined. Abnormal results for each spirometry index were determined by comparison to their lower limits of normal (LLN). The values of FEV<sub>1</sub>, FVC and FEV<sub>1</sub>/FVC were used to categorize pulmonary function patterns as normal, obstructive, restrictive or mixed obstructive and restrictive based on American Thoracic Society/European Respiratory Society (ATS/ERS) guidelines.



**Figure 3. 1: ATS/ERS Algorithm for interpreting Spirometry results.**

Abbreviations: FEV<sub>1</sub> = forced expiratory volume in 1 second; FVC = forced vital capacity; TLC = total lung capacity; LLN = lower limit of normal.

### **3.9.4 Induction of Spinal Anaesthesia**

Baseline standard non-invasive monitoring, including electrocardiography, noninvasive blood pressure, pulse oximetry and temperature, using Carescape Monitor B650 (GE, Finland) was established. Blood pressures, oxygen saturation of haemoglobin and heart rates were recorded. Spinal Anaesthesia was induced in the sitting position with 3mls of 0.5% heavy bupivacaine (15mg) and 0.5ml (25mcg) of fentanyl given over 15 seconds using gauge 26 pencil point spinal needles. This was preceded by skin infiltration with 2ml of 1% lidocaine, at L4/L5 intervertebral space. Spinal Anaesthesia was performed under aseptic conditions. After induction of Anaesthesia, participants were immediately placed in the supine position with the head elevation at 30 degrees. The level of the sensory block was checked every minute, using pinprick/alcohol prep till a stable sensory level between T8-T5 to cold and pain was achieved. A modified Bromage score was assessed and recorded according to standard guidelines to elicit the level of muscle weakness (motor block).

Blood pressure was measured every 3 min for the first 30 minutes and then every 5 min for the rest of the surgery. Presence or absence of adverse effects of spinal Anaesthesia ( difficulty in breathing, nausea and vomiting, palpitation, headaches, dizziness, hypotension, bradycardia, dysrhythmias and shivering) was recorded every 5 minutes till the end of the procedure on a structured complication tool (see Appendix III) and rescue doses of ephedrine (10mg) and atropine (1mg) was given where needed and recorded. To cater for fluid maintenance and replacement of deficit, IV crystalloids were given intraoperatively at 500mls/hour using electronic infusion pump (DRE AVANTI NXT3, USA). A bolus of 100mls administered as rescue doses where the need arises. Arterial blood gas sampling and spirometry reading were

taken in the supine position with the head elevated at 30 degrees at 30 min post-SA respectively. At the end of the surgery, the patient was transported to the recovery suite. Bromage score was assessed every 30min at the recovery suit until a score of zero (0) was attained indicating the patient had recovered fully from SA. At this point, arterial blood gas sampling and spirometry measurements were done. Patients were given pain relief post-surgery to attain pain score less than six (6) on the numerical rating scale. This was done after the patient was instructed to indicate on the pain rating scale (numerical rating scale –NRS) from zero (0) to ten (10) what best described his/her current level of pain post-surgery. A score of zero meant ‘no pain’ and a score of ten (10) meant ‘worst pain’

### **3.9.5 Data handling**

Data collected for the study was used for the intended purposes only. All members of the research team treated all data with strict confidentiality. Data were entered in an MS Access and exported to MS Excel and Statistical Package for Social Sciences (SPSS) version 23 after cleaning. To ensure data security, the following strategies were used:

- 1) Confidentiality was maintained by using unique serial numbers.
- 2) Patient identifiers (name, date of birth and contact information) were decoupled from the rest of the database. This data was entered into an MS Access database and encrypted/password protected. Only the principal investigator and supervisors had access to the database and password.
- 3) Hard copies of personally identifying data and codebook were kept in a locked filing cabinet at the PI’s office.

- 4) The rest of the data (anonymized) was entered in a separate MS Access file (to be exported into excel and/or SPSS for analysis). All data files (MS Access, MS Excel and SPSS) were encrypted and password protected. Anonymized data was only assessable to the PI, supervisors, and statistician.
- 5) Physical restriction to hard copies of patient's non-identifiable data (questionnaires, physical examination forms and laboratory investigations) was ensured. All hard copies were securely locked in a locked filing cabinet at the Department of Physiology research laboratory, University of Ghana School of Biomedical and Allied Health Sciences. Only the principal investigator and supervisors had access to the lock keys.
- 6) Logical security techniques were ensured when working on the internet. These included securing our networks with firewalls and running antispyware and virus-detection programs on our research computers
- 7) Data was backed up on a separate computer situated at the Department of Physiology Research laboratory. The back-up frequency was done daily during the period of data entry.

### **3.9.6 Statistical analysis**

Data were analyzed by using the IBM Statistical Package for Social Sciences (SPSS) version 23 software package. Continuous data including Age, ABG, and pulmonary function were summarized as mean and standard deviation. Categorical data were presented as frequency (percentage) and graphs for variables such as Gender, marital status, ethnicity, occupation and spinal Anaesthesia related complication. Repeated – Measure ANOVA was used to analyze the

difference in pulmonary function over the study period (baseline, intraoperative and recovery) following spinal Anaesthesia.

Logistic regression was used to study the association between baseline (and changes in) pulmonary functional indices and SA-related complication, with adjustments for potential covariates. A 95% confidence interval was used and a p-value  $<0.05$  was considered as statistically significant. Presentation of graphs was done with Microsoft office Excel 2010.

### **3.10 Dissemination of information**

A presentation on my findings was made to the Department of Physiology of SBAHS, University of Ghana. Members of other departments in SBAHS and the Korle-Bu Teaching Hospital were invited to attend this seminar. Similarly, presentations were made at the department of Anaesthesia and intensive care of the Greater Accra Regional Hospital (GARH), Ridge. This will also be disseminated at Ghana Health Service organized scientific conferences and Annual General meetings/conferences of Anaesthesia caregivers to enhance policy formulation. Copies of the study will be placed in the various tertiary institution libraries, including the library of the College of Health Sciences of The University of Ghana, and the Balme library of the University of Ghana. Sections of this study will be published in national and international peer-reviewed journals. Presentations on research findings at scientific workshops, seminars and other conferences will also be done.

## **CHAPTER FOUR**

### **4.0 RESULTS**

A total of fifty (50) patients were recruited for the study but two patients could not perform the spirometry intraoperatively due to change in position during surgery. A complete data of 48 participants were available and this was used for data analysis. The results were presented in text, tables and figures as follows;

#### **4.1 Socio-demographic characteristics**

The socio-demographic characteristics were taken and presented in table 4.1

Two participants representing 4.2% were in the other tribe (Sisala and Wala) as shown in table 4.1. Participants who had no previous exposure to Anaesthesia were 64.4%. Few participants had allergies. Notable among the allergies recorded was an allergy to dust, perfumes, corn dough and okra. Forty-five (93.8%) of the participant were not having any medical condition.

The age of participants ranged from 18 to 59years with a mean of  $38.71 \pm 11.05$  years (figure 4.1). Most participants were within 30-40years of age.

**Table 4. 1: Socio demographic characteristics<sup>1</sup>**

		Frequency (%); n=48
Gender	Male	30 (62.5%)
	Female	18 (37.5%)
Marital status	Never married	18 (37.5%)
	Married	30 (62.5%)
Ethnicity	Akan	25 (52.1%)
	Ewe	5 (10.4%)
	Ga/Dangbe	14 (29.2%)
	Mole/Dagomba	1 (2.1%)
	Gruma	1(2.1%)
	Others	2 (4.2%)
Educational background	No formal	8 (16.7%)
	Basic	13 (27.1%)
	Secondary	12 (25%)
	Tertiary	15 (31.3%)
Employment status	Student	4 (8.3%)
	Employed	44 (91.7%)
	Unemployed	0 (0%)
Smoking status	Never smoked	45 (93.8%)
	Currently smokes	3 (6.2%)
Allergies	Yes	5(10.4%)
	No	43 (89.6%)
Alcohol use	Never	24 (50%)
	Occasional	23 (47.9%)
	Regular	1 (2.1%)
Hypertension	Yes	3 (6.3%)
	No	45 (93.8%)
Previous Anaesthesia	GA	2 (4.3%)
	SA	15 (31.3%)

<sup>1</sup>Data presented as frequency distribution table. Most participants were males 30(62.5%)  
GA= General Anaesthesia, SA= Spinal Anaesthesia

## Socio-demographic characteristics

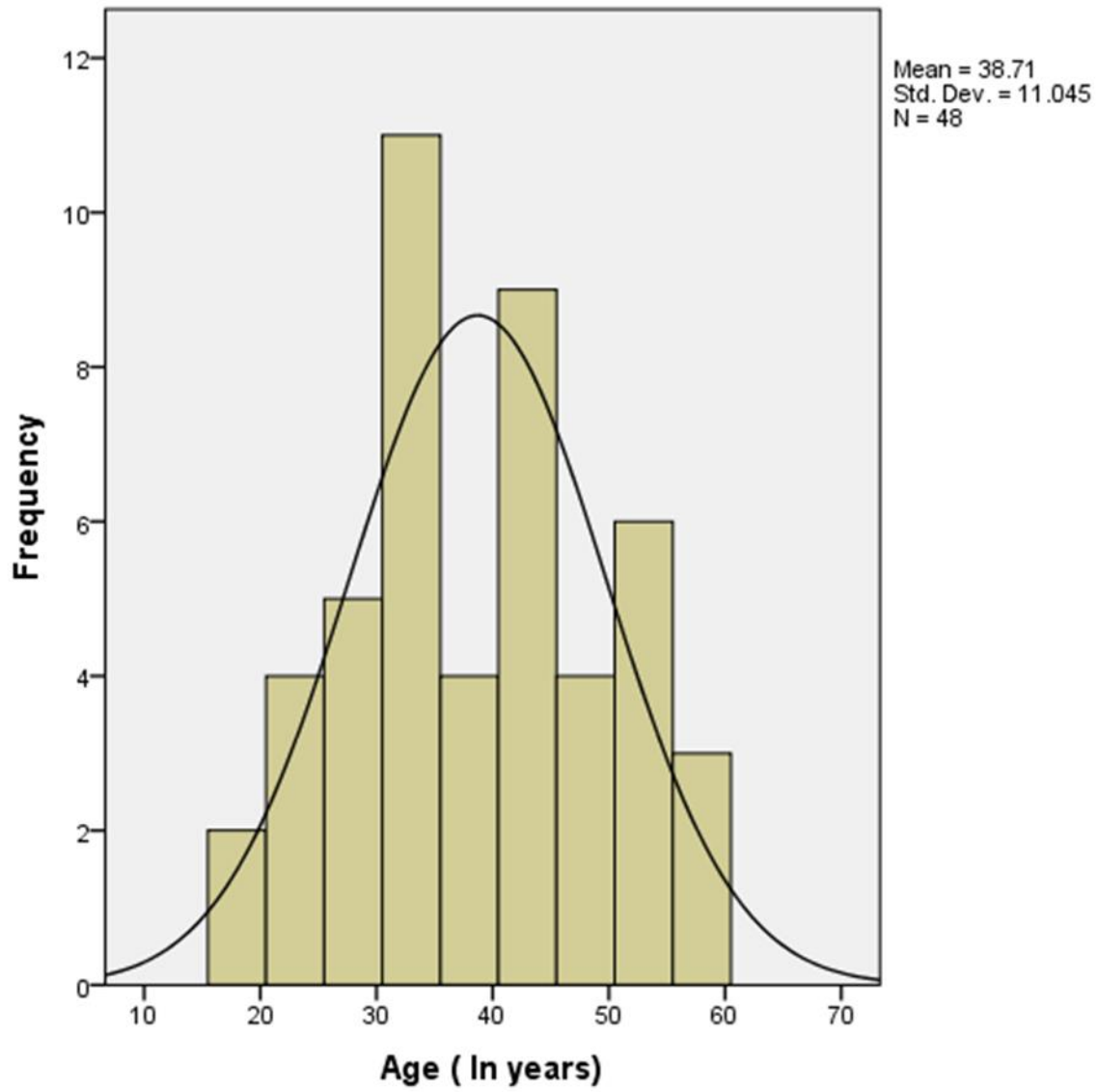


Figure 4. 1: Mean Age of participants

#### 4.1.1 Anthropometric and other Indices

The Mean Body Mass Index (BMI) of the participants ranged from 18.55 to 36.42 Kg/m<sup>2</sup> with a mean of 25.15± 4.19 Kg/ m<sup>2</sup>.

The level of sensory block recorded was from 6th thoracic (T6) to 10th thoracic level (T10). Participants who had a sensory block at T6 level after induction of spinal Anaesthesia were 41.7% whereas 33.3% and 18.8% had a sensory block at T8 and T10 levels respectively.

The minimum and maximum recovery time from Anaesthesia were 60min and 270 min respectively with a mean time of recovery of 143.8±41.0 min as recorded with the modified Bromage score sheet (see table 4.2).

Numerical rating scale (NRS) was used to assess the level of pain of participants post recovery from SA. A score of 10 denotes worst pain and a score of zero (0) indicate no pain. The maximum and minimum pain score of participants were 4/10 and 1/10 respectively with a mean score =2.0±1.0.

**Table 4. 2: Bromage score post-surgery<sup>2</sup>**

Bromage Score	N	Minimum	Maximum
Bromage score at 0 minute (end of surgery)	48	2	3
Bromage score at 30 minutes (post-surgery)	48	1	3
Bromage score at 60 minutes (post-surgery)	48	0	3
Bromage score at 90 minutes (post-surgery)	48	0	3
Bromage score at 120 minutes (post-surgery)	48	0	3
Bromage score at 150 minutes (post-surgery)	48	0	2
Bromage score at 180 minutes (post-surgery)	48	0	2
Bromage score at 210 minutes (post-surgery)	48	0	2
Bromage score at 240 minutes (post-surgery)	48	0	2
Bromage score at 270 minutes (post-surgery)	48	0	0

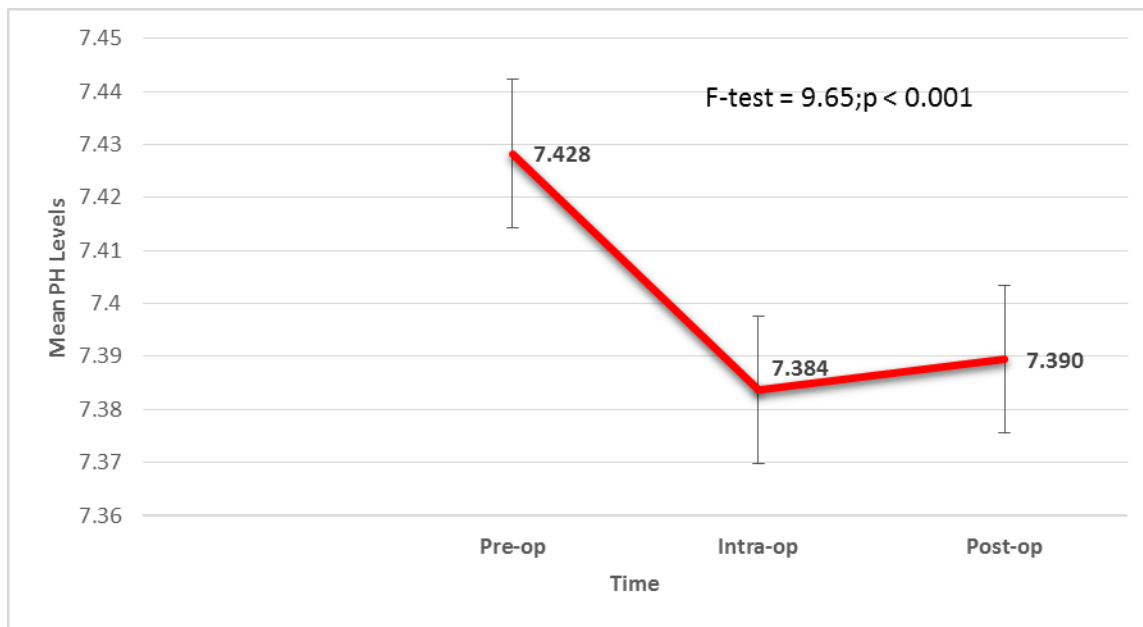
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<sup>2</sup> Frequency distribution of duration of Bromage(motor) score post-surgery.

## 4.2 Pulmonary function of Study Participants

### 4.2.1 Mean Arterial blood gas results

From a follow-up pairwise comparison test, the preoperative mean  $P^H$  (7.428) was significantly higher than the intraoperative mean  $P^H$  (7.384) ( $p$ -value=0.002) and postoperative  $P^H$  (7.390) ( $p$ -value <0.001). Even though there was an increase in the postoperative (at a full recovery from spinal) mean  $P^H$  compared to intraoperative  $P^H$ , this increase was not statistically significant ( $p$ -value= 1.000) (see figure 4.2).



**Figure 4. 2: Perioperative  $P^H$  changes based on estimated marginal means**

## Arterial blood gas results

The preoperative (baseline) PaO<sub>2</sub> showed a slight increase in intraoperatively (30minutes post-spinal) and a reduction postoperatively (full recovery from spinal). There was an increase in PaCO<sub>2</sub> intraoperatively and a marginal reduction postoperatively. A reduction in SaO<sub>2</sub> was observed intraoperatively from preoperative and steadily increased on recovery from spinal Anaesthesia. All these changes were not statistically significant (table 4.3).

**Table 4. 3: Mean perioperative Arterial blood Gas changes<sup>3</sup>**

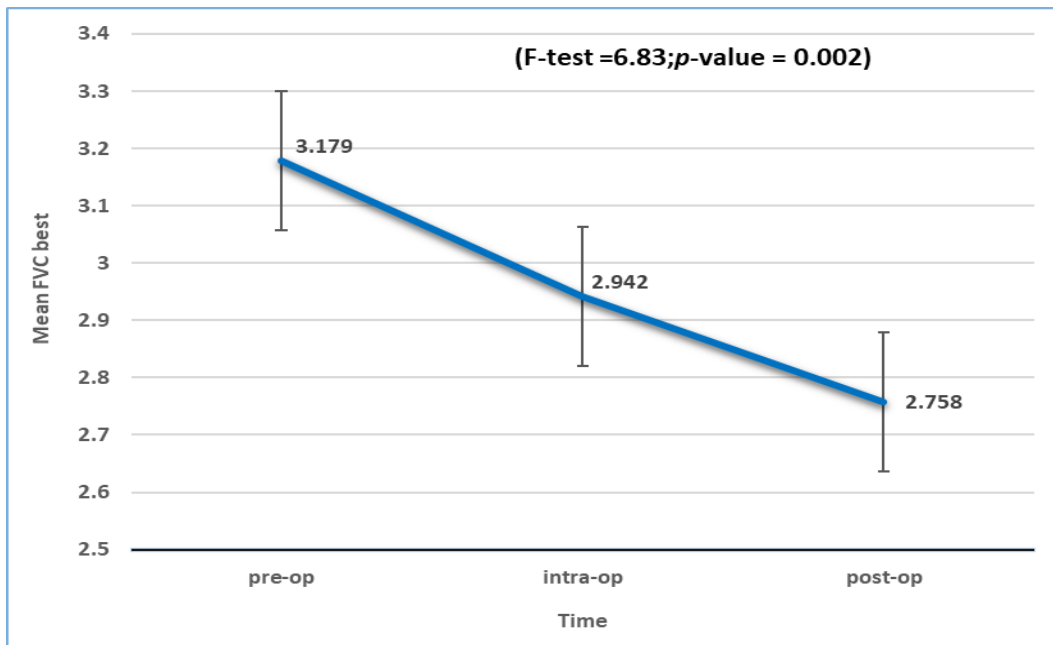
Variable	Category	mean±SD	F test	p-value
PaO <sub>2</sub>	Pre-op	136.86±33.62	1.56	0.216
	Intra-op	139.60±40.66		
	Post-op	127.68±40.18		
PaCO <sub>2</sub>	Pre- op	35.69±4.70	1.49	0.231
	Intra- op	37.71±5.53		
	Post-op	36.78±7.61		
SaO <sub>2</sub>	Pre-op	98.85±0.99	1.89	0.157
	Intra-op	96.58±9.22		
	Post-op	97.93±6.79		

<sup>3</sup> Data is presented as mean (± standard deviation). *p*- value ≤ 0.05 is considered statistically significant. Repeated measure ANOVA was used

PaO<sub>2</sub> =partial pressure of arterial oxygen, PaCO<sub>2</sub>= partial pressure of arterial carbon dioxide, SaO<sub>2</sub>= arterial oxygen saturation, pre-op= preoperative, intra-op= intraoperative, post-op=postoperative

#### 4.2.2 Perioperative mean spirometry indices

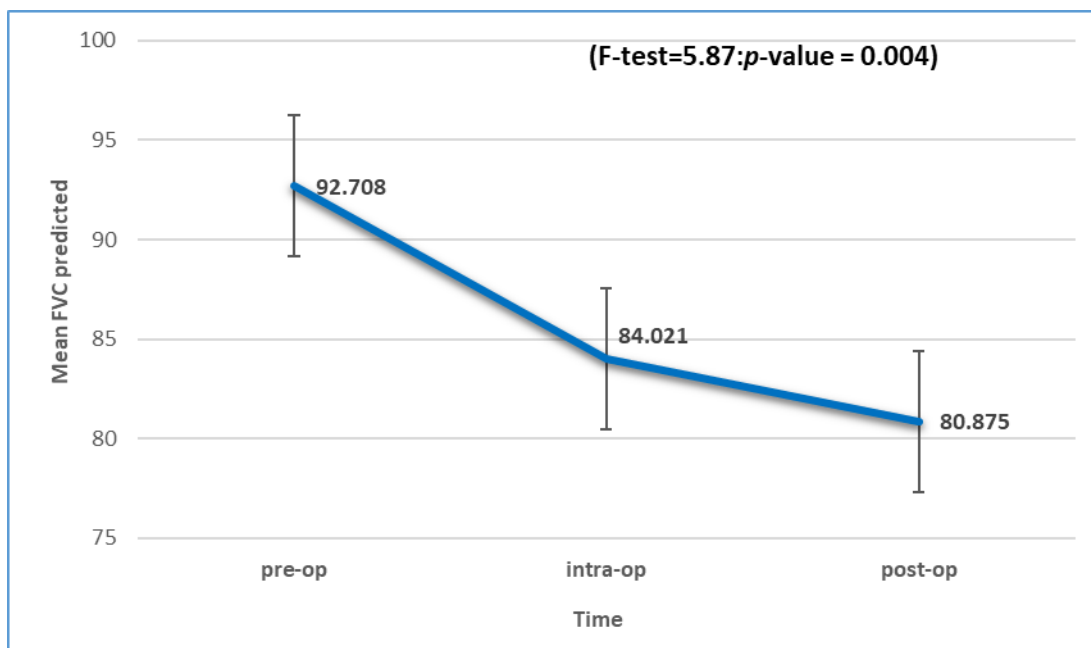
Participants did a spirometry test preoperatively (baseline), intraoperatively (30minutes post-spinal) and postoperatively (full recovery from spinal). The baseline indices were categorized as FEV1/FVC<70% (or LLN) and FVC<80% predicted (or<LLN) which represents obstructive and restrictive defects respectively. All participants 48(100%) did not have any obstructive defect whereas 15(31%) recorded a mild restrictive defect ( $\geq 60$ -80%) preoperatively. The mean Spirometry indices as a parameter of pulmonary function are presented as graphs and tables below. There was a reduction ( $p$ -value=0.002) in mean FVC (best) following spinal Anaesthesia (figure 4.3). However, from a follow-up pairwise analysis, the reduction was noted to be significant only postoperatively ( $p$ -value=0.004)



**Figure 4. 3: Changes in mean FVC (best) following spinal Anaesthesia**

### Perioperative mean spirometry indices

There was a reduction (92.17, 84.02, 80.86) preoperative, intra operative and postoperative respectively ( $p$ -value=0.004) in mean FVC (predicted) (figure 4.4). However, a follow-up pairwise/Bonferroni analysis revealed only a significant reduction postoperatively ( $p$ -value=0.014)



**Figure 4. 4:** Changes in Mean FVC (predicted) following spinal Anaesthesia

### Perioperative mean spirometry indices

Following spinal Anaesthesia, there was a non-significant increase in FVC (LLN) intraoperatively and a non-significant decrease in FVC (LLN) postoperatively (table 4.3)

Following spinal Anaesthesia, there was a non-significant reduction in both FEV<sub>1</sub>/FVC (best) and FEV<sub>1</sub>/ FVC (predicted) intraoperatively and a non-significant increase postoperatively towards preoperative measures. (table 4.4)

**Table 4. 4: Perioperative mean spirometry Indices<sup>4</sup>**

Variables	Category	mean±SD	F test	p-value
FVC(LLN)	Pre-op	2.50±0.68	1.39	0.254
	Intra-op	2.58±0.76		
	Post-op	2.48±0.66		
FEV1(LLN)	Pre- op	2.11±40.54	1.15	0.320
	Intra- op	2.17±0.61		
	Post-op	2.12±0.14		
FEV1/FVC(Best)	Pre-op	85.88±7.79	0.99	0.377
	Intra-op	84.10±8.09		
	Post-op	85.21±7.98		
FEV1/FVC(LLN)	Pre-op	75.90±2.27	0.61	0.543

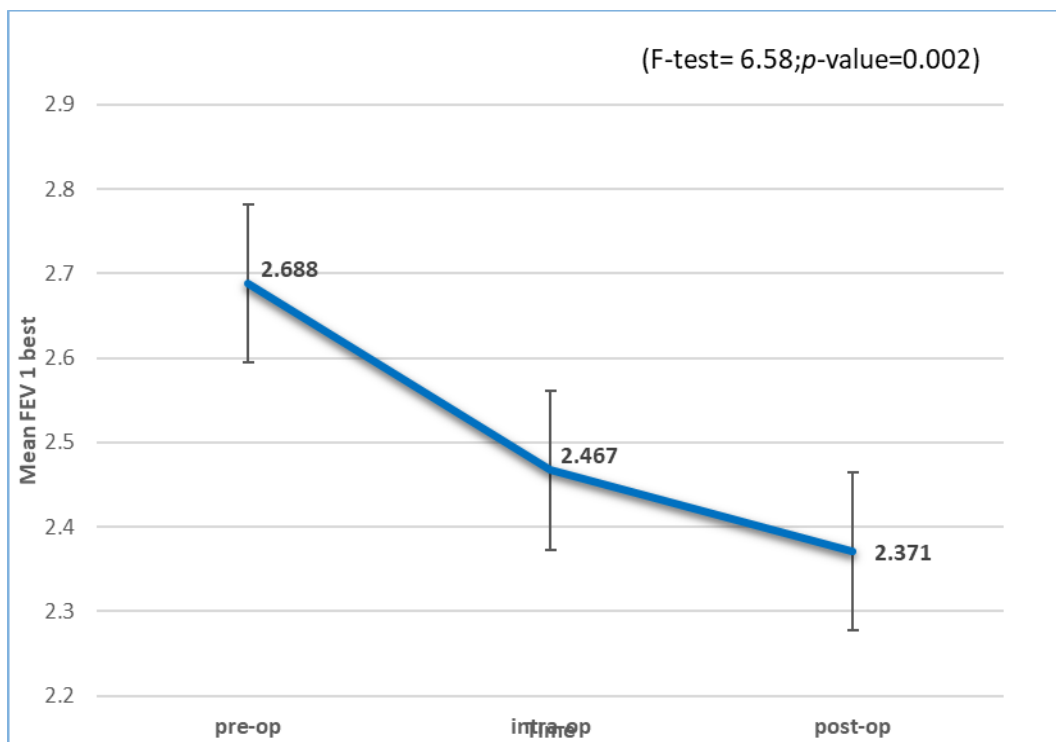
<sup>4</sup> p- value ≤ 0.05 is considered statistically significant. Repeated ANOVA measure was used  
 FVC= forced vital capacity, LLN= lower limit of normal, FEV<sub>1</sub>= forced expiratory volume in one second, PEFR= expiratory flow rate, PRED= predicted, Pre-op= preoperative, intra-op= intraoperative, post-op= postoperative

	Intra-op	75.87±2.45		
	Post-op	76.08±2.21		
FEV1/FVC(PRED)	Pre-op	102.94±9.77	0.95	0.389
	Intra-op	100.83±9.64		
	Post-op	101.96±10.15		
PEFR(LLN)	Pre-op	4.14±0.98	0.023	0.977
	Intra-op	4.15±0.99		
	Post-op	4.13±1.01		

### Perioperative mean spirometry indices

Following spinal Anaesthesia, there was a reduction ( $p$ -value=0.002) in FEV<sub>1</sub> (best) (figure 4.5).

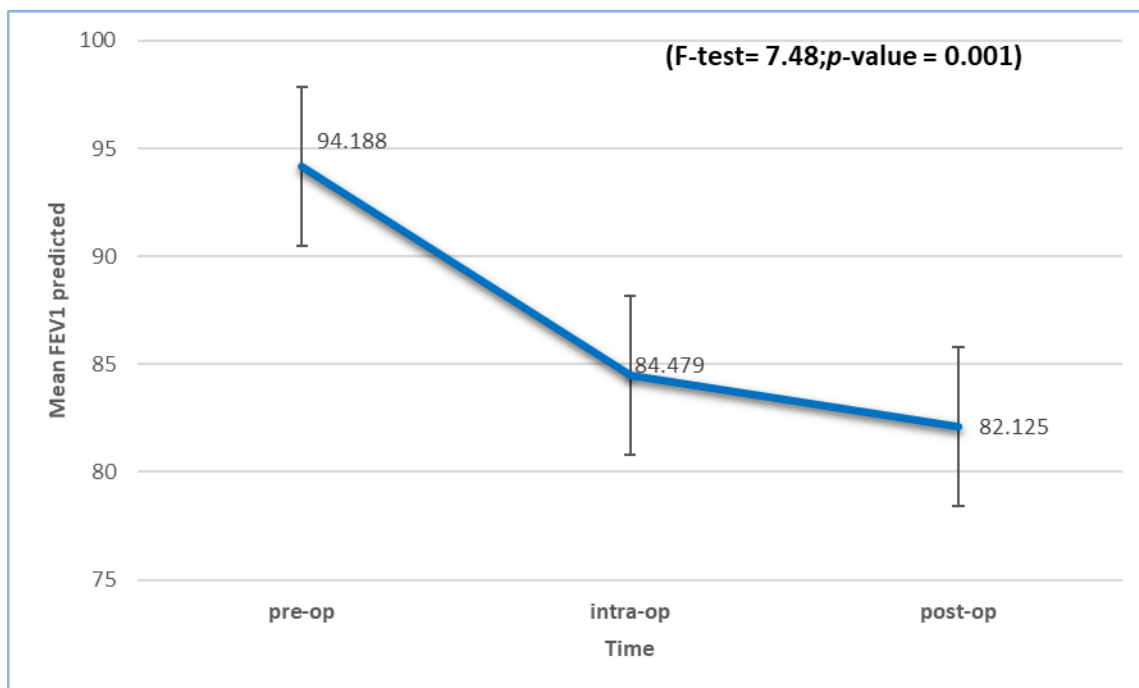
Following a pairwise comparison analysis with Bonferroni, there was a significant reduction postoperatively ( $p$ -value=0.007)



**Figure 4. 5: Changes in mean FEV<sub>1</sub> (best) following spinal Anaesthesia**

### Perioperative mean spirometry indices

There was a significant reduction ( $p$ -value=0.001) in mean FEV<sub>1</sub> (predicted) (figure 4.6). A follow-up (Bonferroni) test showed a statistically significant difference between the preoperative and intraoperative and preoperative and postoperative FEV<sub>1</sub> (predicted) with  $p$ - values ( $p$ =0.026) and ( $p$ =0.010) respectively. However, the difference between intraoperative and postoperative FEV<sub>1</sub> (predicted) was not significant ( $p$ =0.877).

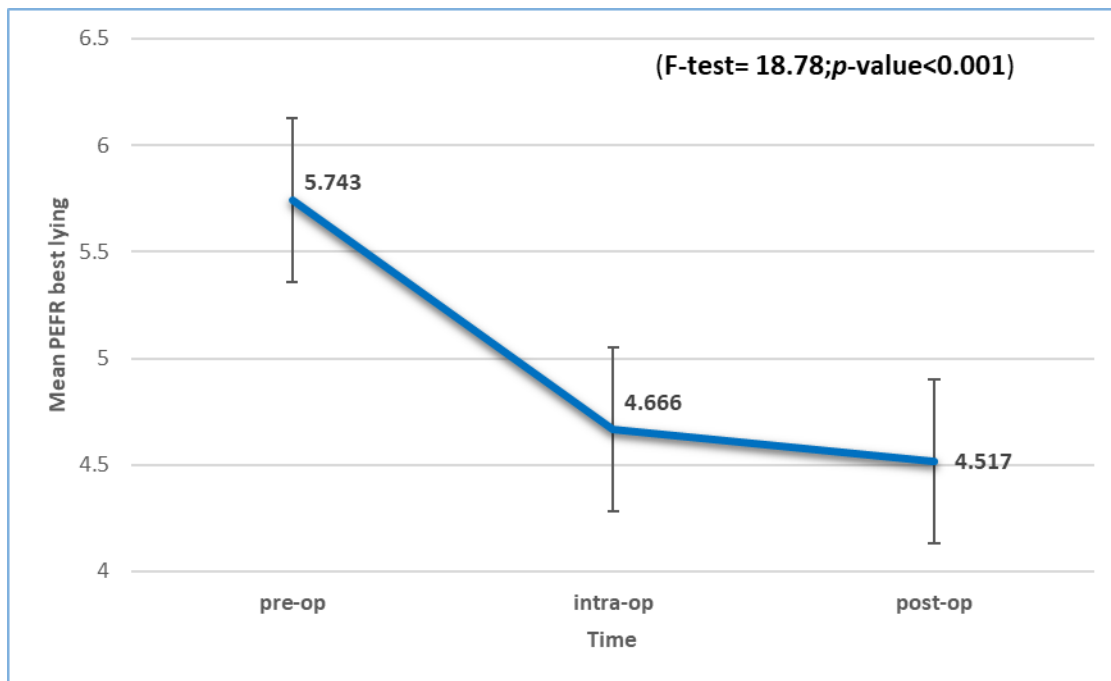


**Figure 4. 6: Changes in Mean FEV<sub>1</sub> (predicted) following spinal Anaesthesia**

### Perioperative mean spirometry indices

There was a significant reduction ( $p<0.001$ ) in PEFR (best) (figure 4.7)

A follow-up pair-wise comparison test showed a significant reduction intraoperatively ( $p<0.001$ ) and postoperatively ( $p<0.001$ ) in PEFR (best) when compared to preoperative values.

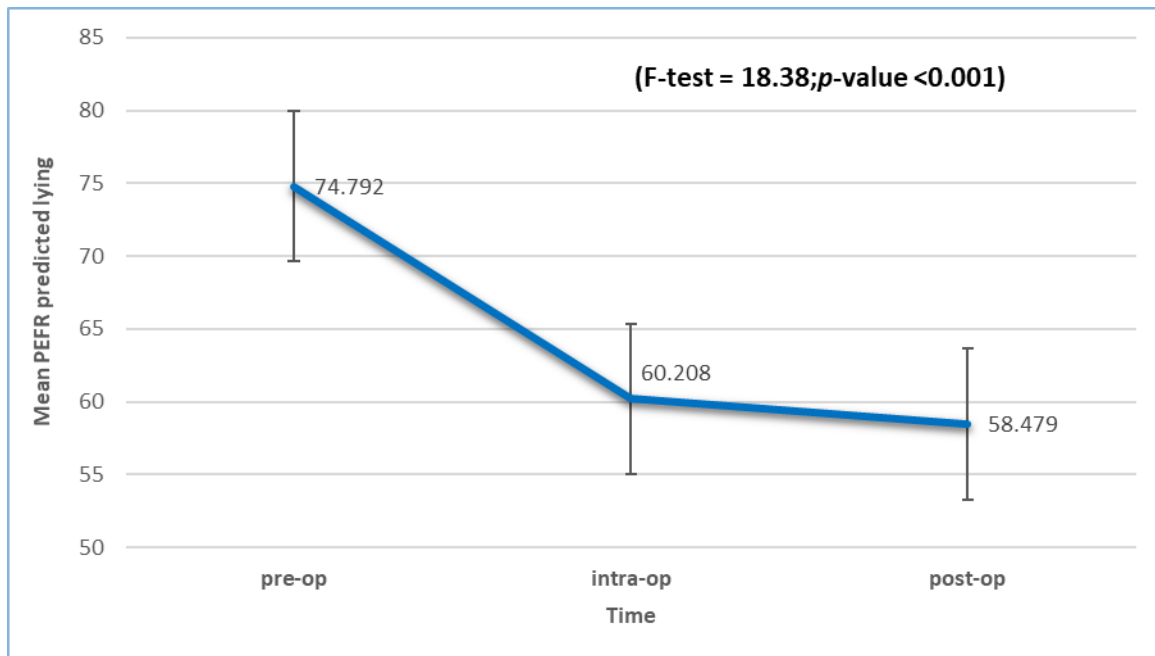


**Figure 4. 7: Changes in Mean PEFR (best) following spinal Anaesthesia**

### Perioperative mean spirometry indices

There was a significant reduction ( $p$ -value $<0.001$ ) in PEFR (predicted) (figure 4.8)

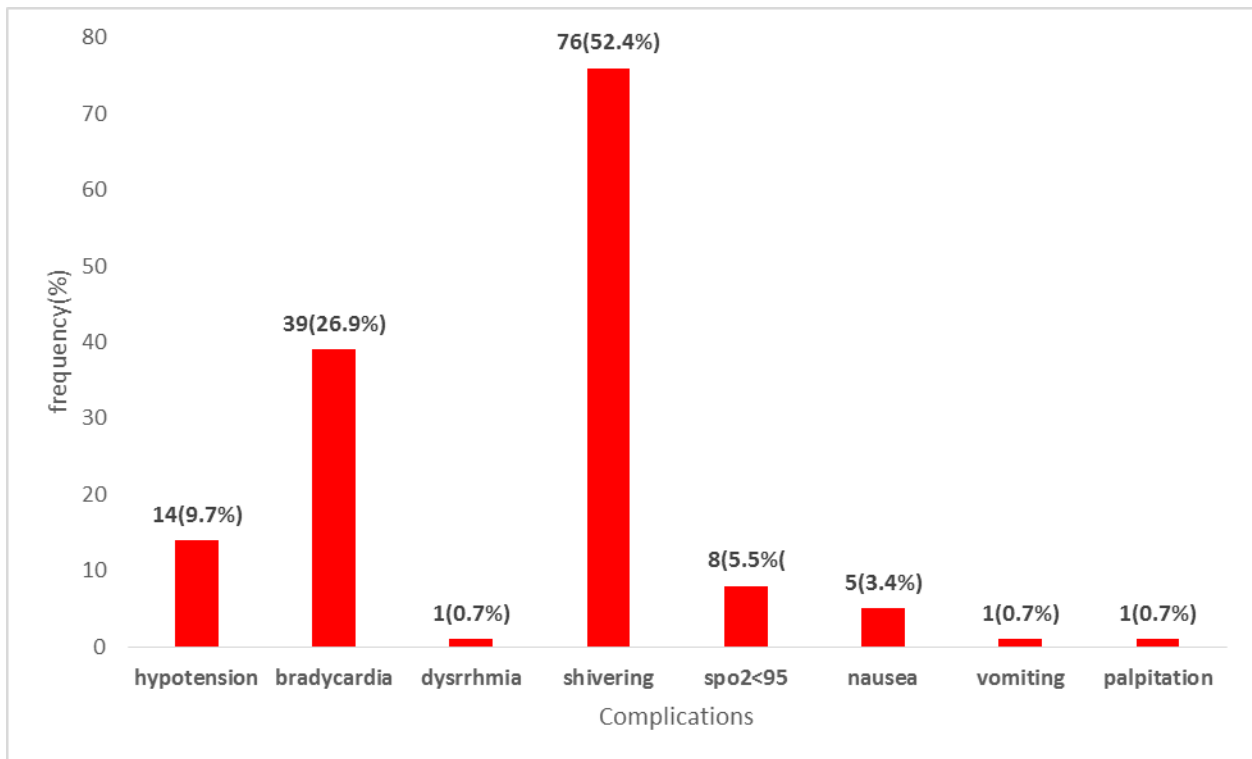
A follow-up pair-wise comparison test showed a significant reduction intraoperatively ( $p$ -value $<0.001$ ) and postoperatively ( $p$ -value $<0.001$ ) in PEFR (predicted) when compared to preoperative values.



**Figure 4.8: Changes in Mean PEFR (predicted) following spinal Anaesthesia**

### 4.3 Occurrence of post- SA related complications

The observed complications following administration of SA were shown in figure 4.9. Spinal Anaesthesia related complication such as shivering, bradycardia and hypotension were observed to be higher with an incidence of 76(52.4%), 39(26.9%) and 14(9.7%) respectively. This graph illustrates the occurrence of SA-related complication from induction to full recovery.



**Figure 4. 9: Post-spinal Anaesthesia related complication**

{Frequency distribution graph; hypotension (SBP<90mmHg or reduction in SBP>40mmHg from baseline; SBP=systolic blood pressure, bradycardia=heart rate less than 60bpm}

### Occurrence of post- SA related complications

Spinal Anaesthesia related complication occurred even after 30min post-spinal to full recovery from Anaesthesia (Table 4.5). The incidence of shivering after 30min post-SA was 26(17.9%) This was low as compared with the incidence of shivering within the first30min post-SA (34.5%)

The total incidence of bradycardia was 39(26.9%) with 26(17.7%) occurring after 30min SA induction to full recovery. Most SA related complications occurred within 31-60min post-spinal Anaesthesia requiring interventions such as intravenous atropine, ephedrine and crystalloids (fluids) administration. However, there was no significant association between post SA duration (after 30min) and the occurrence of intraoperative and postoperative complications. Fisher's exact test= 29.04;  $p=0.274$

**Table 4. 5:Spinal Anaesthesia related complications post 30min and interventions<sup>5</sup>**

Complication	Time (minutes)				
	Frequency (%)				
	31-60	61-90	91-120	>120	MBS=0
Bradycardia	3(6.3)	7(14.6)	5(10.4)	5(10.4)	6(12.5)
Hypotension	3(6.3)	2(4.2)	0(0.0)	0(0.0)	2(4.2)
Shivering	11(22.9)	8(16.7)	4(8.3)	2(4.2)	1(2.1)

<sup>5</sup> Incidence of spinal Anaesthesia related complication after30min to full recovery from Anaesthesia bradycardia and shivering highest incidence in after 30min post SA  
 $p=0.274 > 0.05$  level of significance (fisher's exact test)  
 SA=spinal Anaesthesia, MBS-Modified Bromage Score, IV-Intravenous

Dyspnoea	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Dysrhythmia	1(2.1)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Nausea	2(2.4)	1(2.1)	0(0.0)	0(0.0)	0(0.0)
Vomiting	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(2.1)
Palpitation	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(2.1)
SpO <sub>2</sub> < 95%	2(4.2)	2(4.2)	0(0.0)	0(0.0)	1(2.1)
Ephedrine	3(6.3)	2(4.2)	0(0.0)	0(0.0)	0(0.0)
Atropine	1(2.1)	0(0.0)	0(0.0)	1(2.1)	0(0.0)
IV Fluids	2(4.2)	1(2.1)	0(0.0)	0(0.0)	0(0.0)

## Occurrence of post- SA related complications

There was a steady significant decrease in mean systolic values ( $p<0.001$ ) and diastolic ( $p=0.001$ ) blood pressures within the first 30min post-spinal Anaesthesia. (figure 4.10). The first 15min was observed to have a peak in a reduction in mean systolic pressure as compared to the last 15min

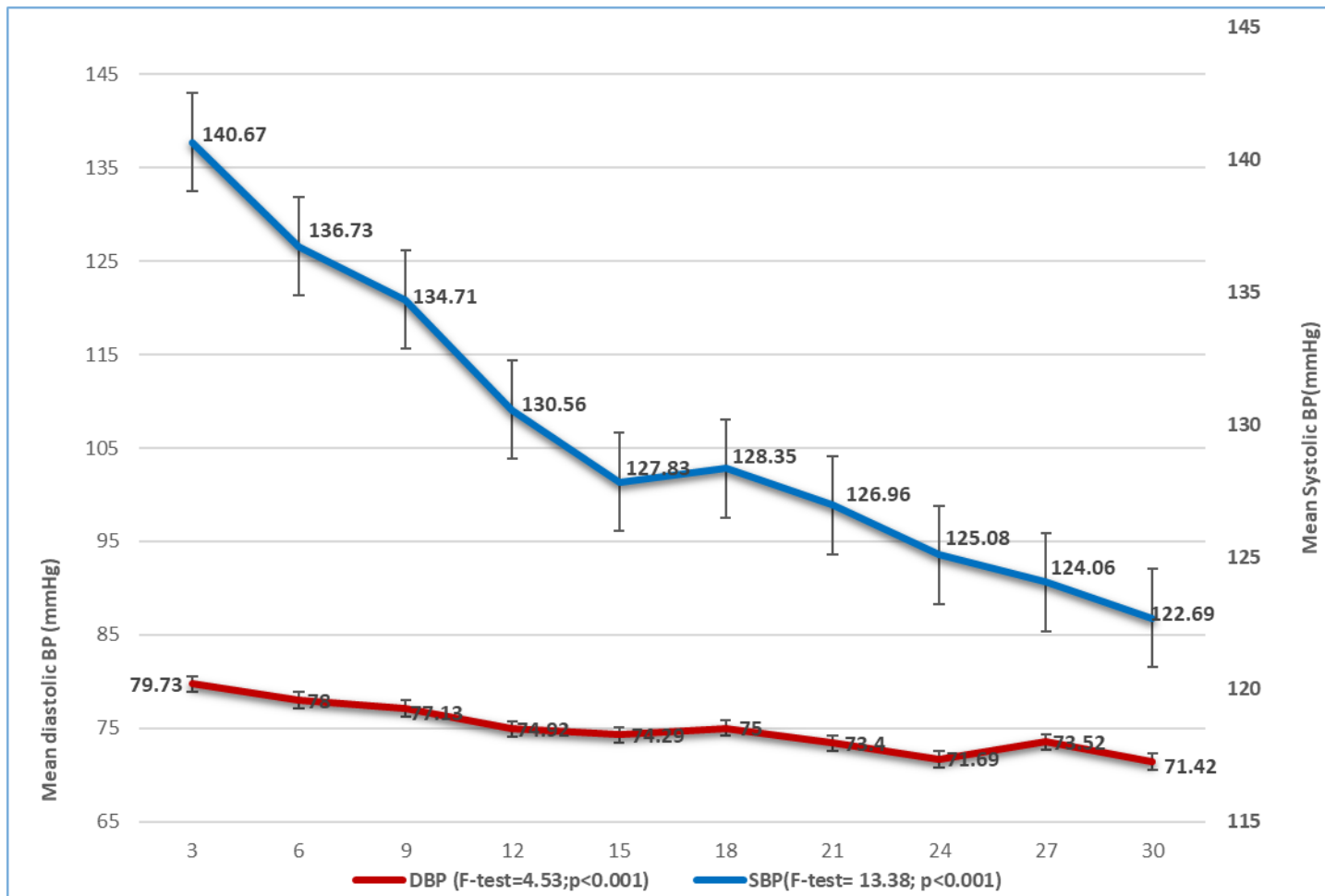
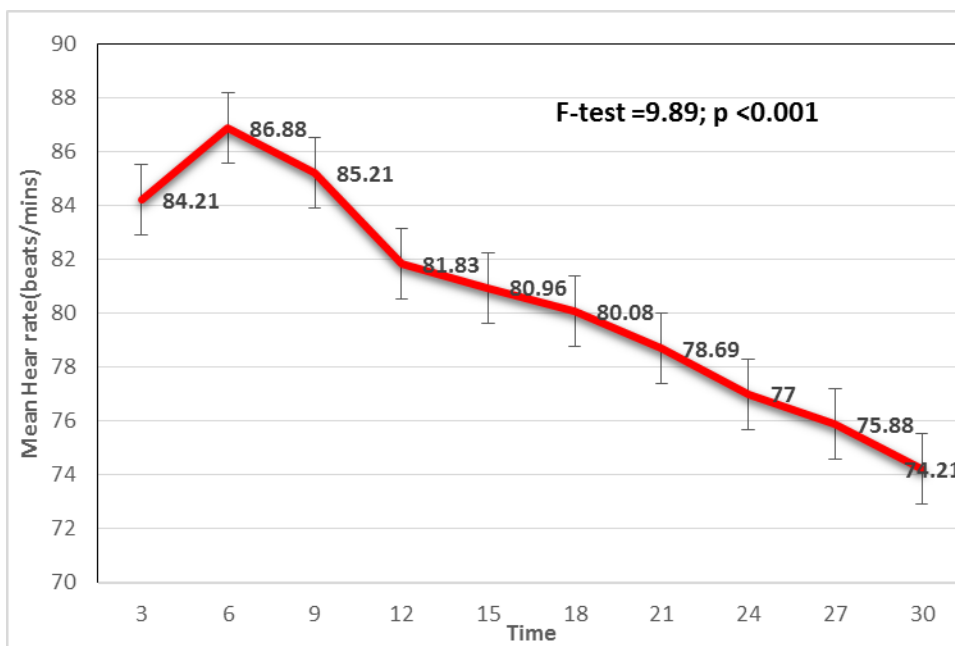


Figure 4. 10: Mean blood pressure during the first 30min post-spinal Anaesthesia

## Occurrence of post- SA related complications

A steep increase was realized immediately after spinal Anaesthesia followed with a steady decline (figure 4.11). Thereafter, a significant reduction ( $p$ -value<0.001) in mean heart rate was noted. The mean reduction in heart rate was observed to be profound between 9 – 12min post-spinal Anaesthesia.



**Figure 4. 11: Mean heart rate during the first 30min following spinal Anaesthesia**

#### 4.4 Pulmonary Function and Spinal Anaesthesia Related Complications

The association between pulmonary function indices and the risk of complications was not statistically significant as shown in table 4.6. However, the odds ratio (>1) indicates spinal Anaesthesia related complications were more likely to occur for a unit change in the pulmonary function of participants. Forced expiratory volume in one second (FEV<sub>1</sub>) and PEFR predicted parameters were paired for pulmonary function changes and Anaesthesia related complication (hypotension, bradycardia and shivering) risk. The results show that FEV<sub>1</sub> (predict) may be more likely to predict the risk of hypotension and bradycardia following spinal Anaesthesia whereas PEFR (predict) may be more likely to predict the risk of hypotension and shivering following spinal Anaesthesia.

**Table 4. 6: Pulmonary function and Risk of developing spinal Anaesthesia related complication<sup>6</sup>**

Variable (predicted)	Category	Hypotension	Bradycardia	Shivering
FEV1preop	Regression co-efficient	-0.026	-0.006	-0.004
	<i>P</i> - value	0.150	0.654	0.737
	OR	0.97	0.99	1.00
	95% CI	(0.94-1.01)	(0.97-1.02)	(0.97-1.02)
FEV1 Intraop	Regression co-efficient	0.003	-0.005	0.001
	<i>P</i> - value	0.930	0.816	0.967

<sup>6</sup> Data was presented using logistic regression. Odds ratio >1.00 indicates risk relationship. Odds ratio ranges from zero to infinity. \*> more likely risk prediction

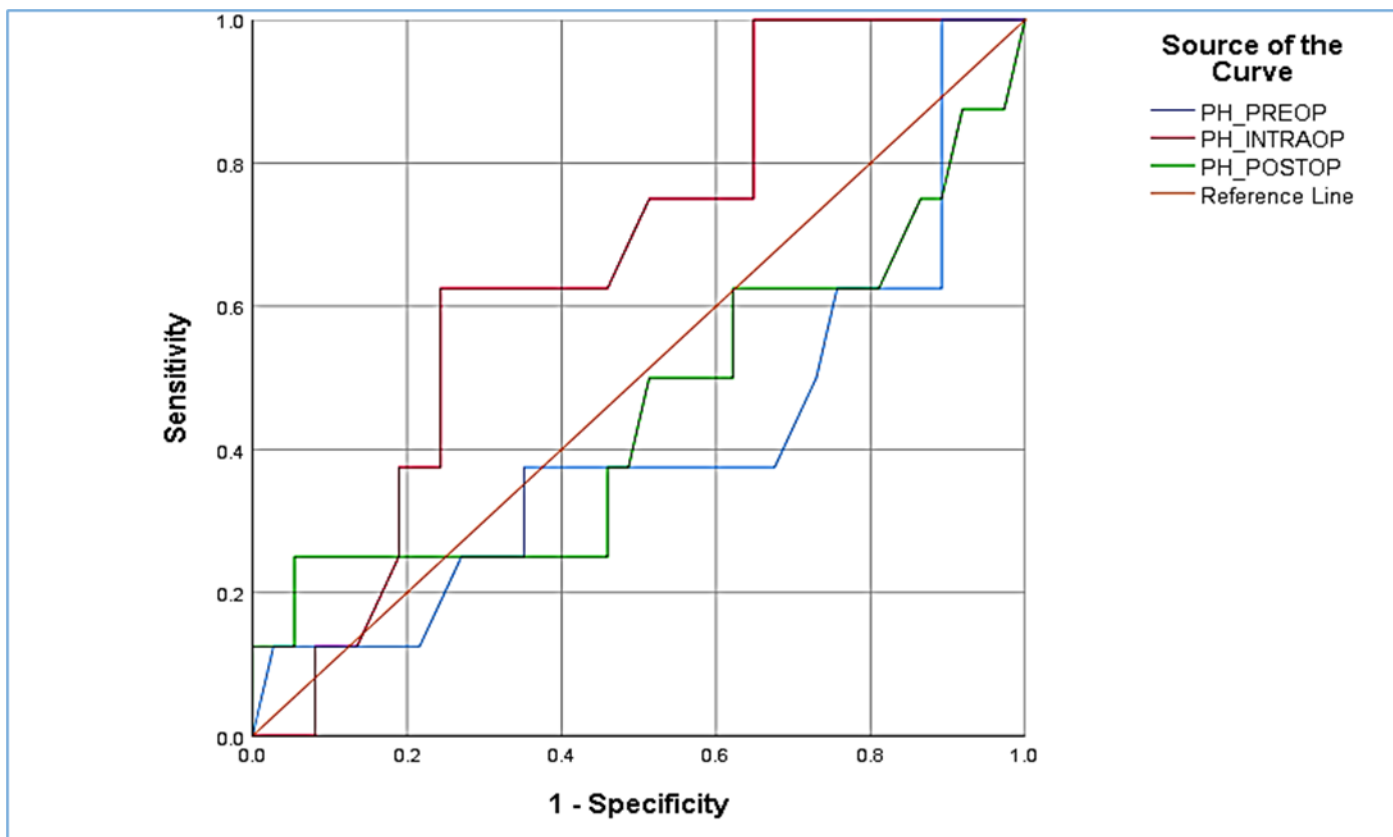
FEV1= forced expiratory volume in one second; PEFR= peak expiratory flow rate; OR= odds ratio; CI= confident interval; pre op= preoperative; intra op= intraoperative; post op= postoperative

	OR	1.00	1.00	1.00
	95% CI	(0.94-1.07)	(0.95-1.04)	(0.96-1.05)
FEV1postop	Regression co-efficient	0.020	0.004	0.009
	<i>P</i> -value	0.501	0.859	0.649
	OR	1.02*	1.00	1.01*
	95% CI	(0.96-1.08)	(0.97-1.04)	(0.97-1.05)
PEFR preop	Regression co-efficient	0.023	-0.018	0.011
	<i>P</i> -value	0.352	0.258	0.471
	OR	1.02*	0.98	1.01*
	95% CI	(0.98-1.08)	(0.95-1.01)	(0.98-1.04)
PEFR intraop	Regression co-efficient	-0.069	-0.007	-0.006
	<i>P</i> -value	0.032**	0.749	0.781
	OR	0.93	0.99	0.99
	95% CI	(0.88-0.99)	(0.95-1.04)	(0.95-1.04)
PEFR postop	Regression co-efficient	0.045	0.005	0.009
	<i>P</i> -value	0.096	0.810	0.645
	OR	1.05*	1.01*	1.01*
	95% CI	(0.99-1.10)	(0.97-1.04)	(0.97-1.05)

## Pulmonary Function and Spinal Anaesthesia Related Complications

The  $P^H$  levels did not indicate a statistically significant relationship with SA related complications although the area under the curve (AUC) depicted the chance of  $P^H$  level to predict the occurrence of SA related complications.

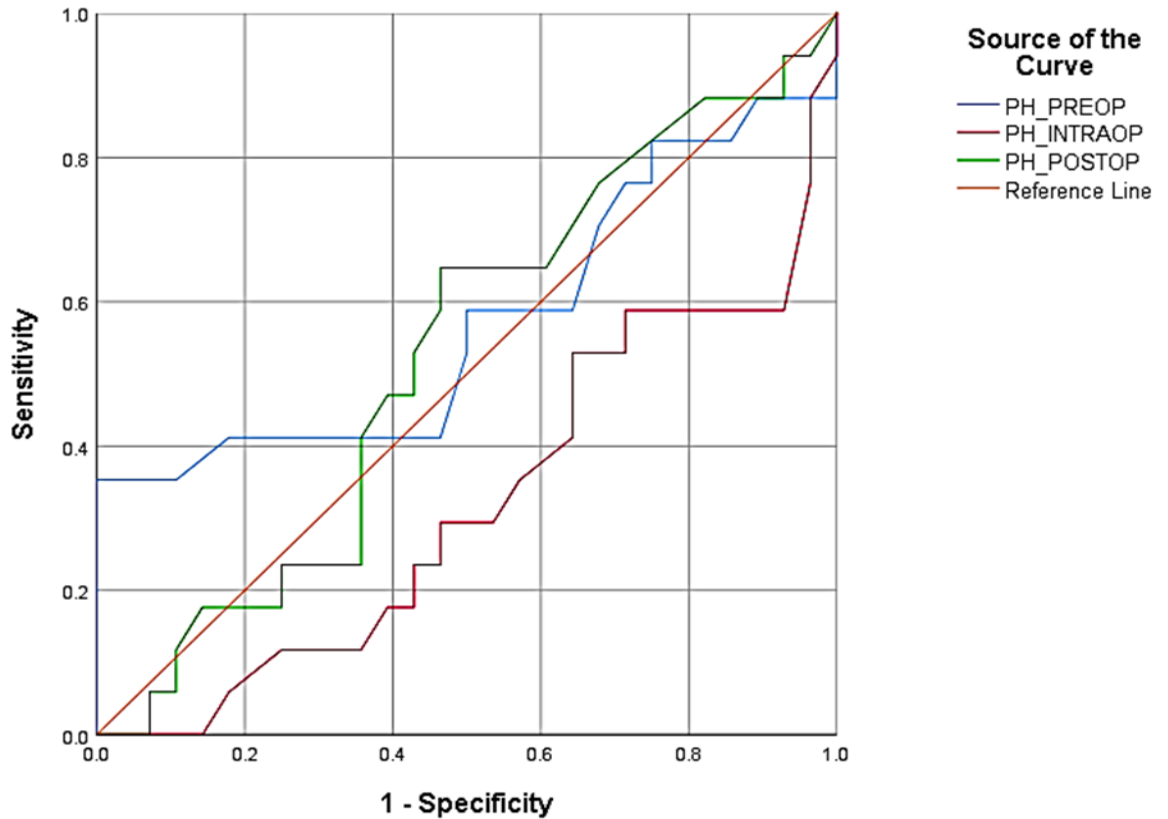
Figure 4.12 shows the sensitivity of  $P^H$  levels to hypotension. The area under the curve for preoperative  $P^H$  was 0.41; intraoperative  $P^H$  0.66 and postoperative  $P^H$  0.45.



**Figure 4. 12 Sensitivity of  $P^H$  levels to Hypotension**

### Pulmonary Function and Spinal Anaesthesia Related Complication

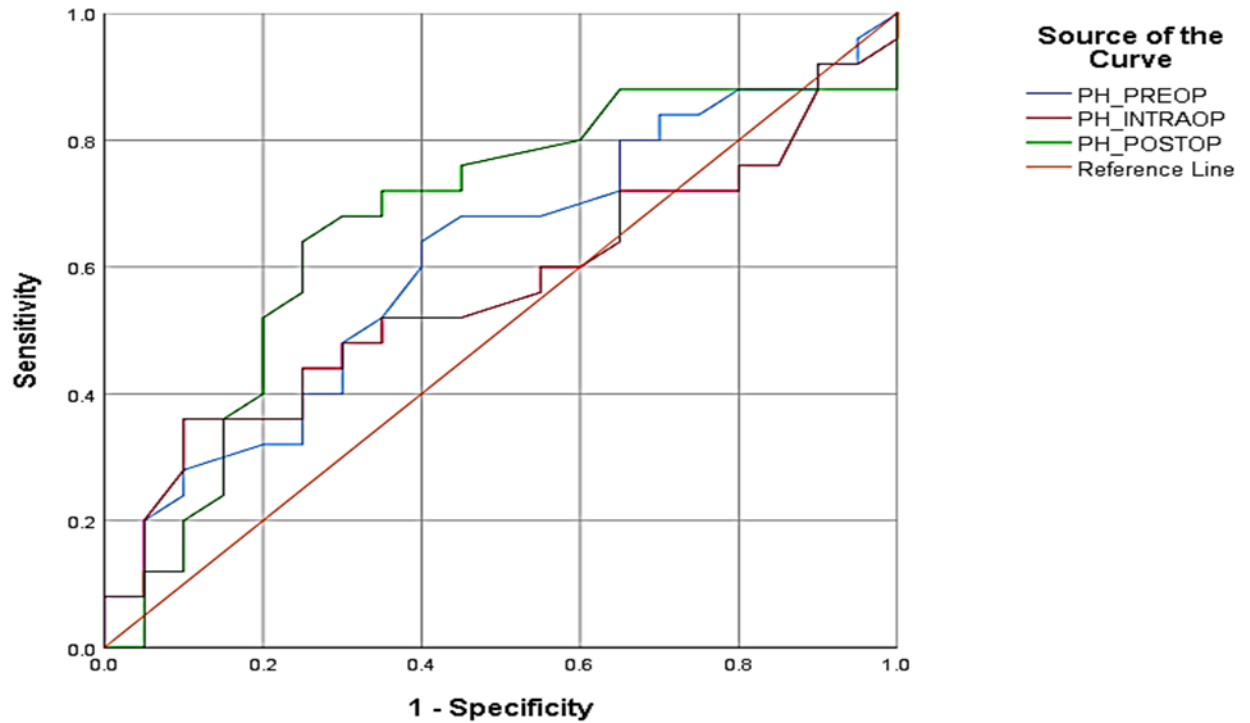
The Receiver Operating Characteristics curve (ROC) (figure 4.13) shows the area under the curve (AUC) for P<sup>H</sup> preoperative, intraoperative and postoperative as AUC=0.51; 0.23; 0.53 respectively to the occurrence of bradycardia.



**Figure 4. 13: sensitivity of P<sup>H</sup> levels to occurrence of Bradycardia**

## Pulmonary Function and Spinal Anaesthesia Related Complication

The AUC shows P<sup>H</sup> preoperative, intraoperative and postoperative as AUC=0.67; AUC=0.56; AUC=0.61 related to the occurrence of shivering respectively (fig4.14)



**Figure 4. 14: sensitivity of P<sup>H</sup> levels to the occurrence of shivering**

## **CHAPTER FIVE**

### **5.0 DISCUSSION, CONCLUSION AND RECOMMENDATION**

#### **5.1 Discussion**

##### **5.1.1 Pulmonary function and spinal Anaesthesia**

Participants who underwent spinal Anaesthesia had significant reduction in mean values of spirometry parameters FVC, ( $p=0.002$ ), FVC (predicted) ( $p=0.004$ ), FEV<sub>1</sub> ( $p=0.002$ ), FEV<sub>1</sub>predicted ( $p=0.001$ ), PEF<sub>R</sub> ( $p=0.001$ ) and PEF<sub>R</sub> (Predicted) ( $p<0.001$ ) as observed in figures 4.2-4.8. All spirometry measured indices reduced following SA. Spinal Anaesthesia blocks respiratory muscle motor fibres. Sensory function is also known to be affected about two dermatomal levels above motor block levels. With the majority of our patients having motor blocks up to T6 to T8 (75%), respiratory compromise evidenced by obstructive and restrictive patterns of lowered measured parameters is understandable. This significant reduction in pulmonary function both intraoperative and postoperatively is consistent with a previous study by (Kelly, Fitzpatrick,1996). In his observational study on the respiratory effect of spinal Anaesthesia, 35 participants were involved. Post spinal Anaesthesia PEF<sub>R</sub>, FVC, FEV<sub>1</sub>, and FEF<sub>25-75%</sub> were significantly reduced when compared to baseline. In their study, the changes in pulmonary function indices persisted even when spinal Anaesthesia effects had worn off. Postsurgical pain was thought to be a contributory factor in their study. Although we observed a similar decline in spirometry indices, many of our patients did not experience significant pain post-surgery. Our minimum and maximum pain score participants registered were 1/10 and 4/10 respectively with a mean score  $=2.0\pm 1.0$ . Therefore, we would hesitate to relate pain to our results.

A similar prospective study by Geng *et al.*, (2014); Regli *et al.*, (2006) agrees that SA significantly reduces FVC but it is contradicted by the current study that FEV<sub>1</sub> and PEFR are equally significantly reduced. Other studies (Arzola & Wieczorek, 2011; Magnusson, 2010; Ostrowska & de Carvalho, 2015) assert that FEV<sub>1</sub> was not decreased as a block lower than T4 does not affect diaphragmatic movement which is the major muscle in inspiration though there may be minimal change in vital capacity. The current study was known to record the highest (41.7%) block of participants at T6 which might not have diaphragmatic involvement primarily but the receptors of the respiratory muscles that assist in expiration like the intercostal and abdominal muscles are affected by SA. This may indirectly affect the discharge to the diaphragm and may affect the work of breathing and impair force of expiration.

There was a decrease in the P<sup>H</sup> (figure 4.2) intraoperatively which was significant (p<0.001) with a corresponding increase in the PaCO<sub>2</sub> intraoperative though the increase in PaCO<sub>2</sub> was not statistically and clinically significant. There was also an increase in PaO<sub>2</sub> intraoperatively from baseline (preoperative) but not significant. The decrease in P<sup>H</sup> and a corresponding increase in PaCO<sub>2</sub> when lung volume parameters were decreased indicated spinal Anaesthesia affects pulmonary function. This indicates an obstruction to expiration which is diagnosed by reduced FEV<sub>1</sub> or PEFR. Carbon dioxide is a strong stimulant of breathing. It is evident that with each 1mmHg increase in PaCO<sub>2</sub> ventilation increases by 2-4 folds litres/min (Weibel Ewald R., 2019).

An increase in the PaO<sub>2</sub> intraoperative may be a result of a response to the increased acidaemia. The impact of spinal Anaesthesia seems to be however transient and parameters are less affected in recovery with return to baseline measures. This agrees with the previous studies which argue

that there are changes but the body mechanism compensates to return the pulmonary function to normal physiological level (Cowley & Owen, 2013; Javaheri & Sicilian, 1992; Kelly, Fitzpatrick, 1996; Pusapati, Sivashanmugam, & Ravishankar, 2010; Wagner, 2015). Pusapati, *et al.*, (2010) reported a significant increase in end-tidal CO<sub>2</sub> from mean 31.68±4.1 to 37.62±4.2mmHg and p=0.000. The arterial partial pressure of carbon dioxide also increased equally without any difference in the two variables within 20min post-spinal Anaesthesia. They concluded that preserved inspiratory diaphragmatic activity maintain gas exchange within physiological limit because participants were conscious.

Other similar studies have shown minimal pulmonary effects (Arzola & Wiecezorek, (2011)& Ituk Unyime, (2018); higher PaO<sub>2</sub> with lower PaCO<sub>2</sub> (Ward *et al.*, 1965); lower PaO<sub>2</sub> (Yamakage, Kamada, Toriyabe, Honma, (1999) and no impact on maternal PaO<sub>2</sub> Kelly, Fitzpatrick, (1996). Some of the studies were undertaken many years ago and the types and dosage of drugs used and spinal techniques may have impacted the different results obtained. Secondly, pulmonary function is shown to have racial and ethnic variations. This current study was conducted in Ghanaians (blacks) which might account for some of the differences in results.

### **5.1.2 Incidence of intraoperative and postoperative complication following spinal Anaesthesia**

Shivering (76%), hypotension (14%) and bradycardia (39%) were the highest incidences of spinal Anaesthesia related complication observed in this current study (figure4.9). These complications extended to post recovery from Anaesthesia. Higher occurrence of bradycardia

was after 30min post-spinal Anaesthesia. The systolic and diastolic blood pressures decreased significantly (figure4.10) within 30min post spinal. Peak decrease in blood pressure was seen in the first 15min post spinal as compared to the last 15min. Also, the reduction in mean heart rate as described in figure4.11 was significant with a peak decrease between 9 and 12min. These changes in patterns of decrease in blood pressure and heart rate over time are consistent with studies previously conducted on the physiological effect of spinal Anaesthesia where 30 participants were recruited (Sukhen *et al.*, 2013). They observed a significant reduction in heart rate within the first 20min of spinal Anaesthesia and a reduction in arterial blood pressure which was statistically significant after 20min post Anaesthesia although hypotension or bradycardia was not observed in their study.

Sudden reduction in blood pressure decreases the baroreceptor activity in the aortic arch and carotid sinus. This then causes a decrease in the stimulation of the cardio regulatory Centre. The body tries to raise the blood pressure by the release of adrenaline. This causes immediate increased contractility and increase in heart rate. This effect was realized as an immediate steep increase in heart rate from our study when the blood pressure suddenly dropped (fig 4.10-4.11). There was a further decrease in both blood pressure and heart rate as a result of reduced afferent response due to spinal Anaesthesia effect on autonomic fibres. Salvatore *et al.*, (1952) also demonstrated an average drop in mean arterial pressure by 21%, stroke volume 25% and a decrease in peripheral resistance with a corresponding increase in heart rate which was similar to our study results. It also agrees with previous literature (Fakherpour, *et al.*, 2018) in their prospective study of 511 participants who underwent elective surgery under spinal Anaesthesia. The incidence of hypotension in their study was categorized as mild, moderate and severe with

their occurrences as 20%, 35% and 40% respectively. High sensory blocks above T4 were implicated.

Shivering (34.5%) mostly occurred within 30min of SA administration. This study result is in line with (Ituk Unyime, 2018; Luggya *et al.*, 2016). According to (Ituk Unyime, 2018) autonomic block are 2-6 dermatomes above sensory blocks. Temperature receptors in the spinal cord may contribute to this effect as many patients often shiver without the sensation of feeling cold. True hypothermia is also possible as Anaesthesia progresses due to the peripheral distribution of blood following vasodilatation. Other literature considers shivering may also be caused by environmental temperature and exposure to surgery (Luggya *et al.*, 2016). However, this study did not consider that although agrees that surgical exposure and cold environment may be a contributory factor to the incidence of shivering in participants. A study in Egypt confirmed the incidence of shivering in the placebo group was 55% (Abdelrahman, 2012).

The current study also observed nausea and vomiting as a related complication which also occurred in a randomised study by (Spelina & Gerber, 1984) and also agrees with a study conducted in Libya where 12% of patients experienced vomiting.

### **5.1.3 Association between pulmonary function and the risk of developing spinal Anaesthesia related complication**

There has been limiting publications on the association of pulmonary function with the risk of developing spinal Anaesthesia related complications.

In this current study, there was no significant difference between pulmonary function and spinal Anaesthesia related complication. This is consistent with previous reviews discussed by (Ciriaco *et al.*, 2000; Lee *et al.*, 2011). However, the odds ratio as summarized in table 4.6 show unit change in FEV<sub>1</sub> (predict) may be more likely to predict the risk of hypotension (OR=1.02) and shivering (OR=1.01). A unit change in PEFr (predict) may be more likely to predict the risk of hypotension (OR=1.02;1.05), bradycardia (OR=1.01) and post-spinal shivering (OR=1.01).

A reduction in pulmonary function parameters FEV<sub>1</sub> and PEFr (predict) respectively results in obstructive abnormalities during expiration. This contributes to the accumulation of alveoli CO<sub>2</sub> and a corresponding PaCO<sub>2</sub> increase with an inverse decrease in pH in those whose ventilator drive is compromised. This mechanism may likely risk the occurrence of bradycardia and hypotension. It may further lead to a profound redistribution of blood to the periphery due to vasodilative activity together with the absence of afferent response because of the spinal block leading to shivering. This is in line with the study by (Mitchell *et al.*, 1972) which postulates the decrease in pH in the absence of sympathoadrenal system such as in SA further results in a decrease in the rate and contractility of the heart.

Many previous cohort studies have revealed that reduction in FEV<sub>1</sub> is a predictor for cardiovascular diseases such as first-time stroke, heart failure, myocardial diseases, atrial fibrillations and even sudden cardiac death. They reported a significant association between FEV<sub>1</sub> and cardiopulmonary complication. Their study results differed from current results because they were conducted in large sample sizes (4700 to 13000) between 5 -7year duration. For instance in one of their study at Copenhagen hospital revealed risk for new atrial fibrillation was 1.8times higher for FEV<sub>1</sub> (Buch *et al.*, 2003; Jacobs *et al.*, 2018; Kurl *et al.*, 2015). Other

studies have contradictory views on this relationship. Studies conducted among Korean adults without airflow limitations reports FEV<sub>1</sub> had no relationship with cardiovascular risk and continued to assert to the fact that it may not be a sensitive tool for predicting complications in people without airway abnormalities (Lee *et al.*, 2011). In another previous study, arterial blood gas levels as an index for pulmonary function were used as predictors for cardiopulmonary complication. This is because P<sup>H</sup> is very sensitive and may predict small changes in a relationship. However, the current results as displayed in figure 4.12 - 4.14 indicated there was no statistically significant relationship between P<sup>H</sup> and SA related complication such as hypotension, bradycardia and shivering which were the highest incidence in this study although P<sup>H</sup> was significantly reduced perioperatively. However, the area under the curve (AUC) depicted the possibility of P<sup>H</sup> level to predict the occurrence of SA related complication. A small reduction in P<sup>H</sup> (acidosis) in the absence of sympathetic compensation due to SA, could lead to vasodilation. This causes myocardial depression and reduction in cardiac contractility which results in hypotension and bradycardia. Further pooling of blood to the periphery resulted in shivering as observed in current study. For instance, figure 4.14, revealed AUC for P<sup>H</sup> preoperative, intraoperative and postoperative as AUC= 0.67; 0.56; and 0.61 respectively related to the occurrence of shivering. A study by Ciriaco *et al.*, (2000) observed that a lower PaO<sub>2</sub> and PaCO<sub>2</sub> could predict the risk of supraventricular arrhythmia. In their study, a PaO<sub>2</sub> of 80.8-85mmHg and PaCO<sub>2</sub> of 35.5 -38.8 mmHg with p=0.04 and p=0.01 respectively were significant to predict cardiovascular complication whiles in that same study where 160 participants were used FVC and FEV<sub>1</sub> could not predict the risk of arrhythmias. This current result is contrary to their findings in that the current studies did not establish any relationship between PaCO<sub>2</sub> and spinal Anaesthesia related complication. Secondly, the current results showed that PO<sub>2</sub> and

PaCO<sub>2</sub> increased intraoperatively. A transient change in P<sup>H</sup> between 7.2-7.3 had been shown to result in myocardial depression in the absence of sympathoadrenal stimulation (Mitchell *et al.*, 1972). This agrees with the current study since SA causes sympathectomy. In their observation, there was no compensatory mechanism from the sympathoadrenal system for the release of catecholamine therefore acidosis caused further vasodilation and resulted in myocardial depression. In this current study, there was no significant association between P<sup>H</sup> and spinal Anaesthesia related complication however, The AUC shows P<sup>H</sup> may be sensitive to predict the occurrence of shivering despite the small sample size.

## **5.2 Summary of findings**

Pulmonary functional changes in patients undergoing spinal Anaesthesia for surgery has been investigated in other countries but no such report has been published in Ghanaian patients.

This study has shown that spinal Anaesthesia affects pulmonary function due to its effects on muscles that affect expiration. This causes a reduction in its respiratory parameters intraoperative and postoperative as result of obstructive abnormalities during expiration.

No published work had observed the relationship between pulmonary function and the risk of development of spinal Anaesthesia complication in surgical patients in Ghana. Even though there was no significant relationship between pulmonary function and spinal Anaesthesia related complication, the odds ratio shows spinal Anaesthesia related complications such as hypotension and bradycardia are more likely to occur for any unit reduction in the FEV1 (predicted) and

PEFR (predicted) while a unit reduction in PEF<sub>R</sub> was more likely to predict the occurrence of shivering.

The hypothesis for this study was for FEV<sub>1</sub> and PaO<sub>2</sub> to be reduced following spinal Anaesthesia. On the contrary, PaO<sub>2</sub> was increased intraoperatively and this needs further studies into the mechanism to elucidate the occurrence

Mean reduction in FEV<sub>1</sub> and PEF<sub>R</sub> both intraoperative and postoperative corresponded with a significant reduction in pH values intraoperative and increase in PaCO<sub>2</sub>.

Shivering was the commonest spinal Anaesthesia related complication. Bradycardia was also shown to persist even after spinal Anaesthesia effect had worn off.

### **5.3 Clinical Relevance of key findings**

Spinal Anaesthesia reduces pulmonary function.

These findings could be used to support previous studies for a measure (routine arterial blood gas analysis) to be taken in patients with already reduced pulmonary function and undergoing surgery under spinal Anaesthesia.

Increased monitoring should be advocated for high-risk surgical patients.

The study has added to knowledge on the prevalence of incidence of spinal Anaesthesia complication in Ghana

Findings from the studies could whip up interest in further studies into the mechanisms that may predict changes in pulmonary function and the risk of post spinal complication

#### **5.4 Conclusion**

Spinal Anaesthesia affects pulmonary function. This causes reduction in FEV<sub>1</sub> intraoperatively and post operatively. Reduction in FEV<sub>1</sub> may be a contributing factor to other mechanisms that result in spinal Anaesthesia related complication. Reduction in FEV<sub>1</sub> may be more likely to predict the risk of development of spinal Anaesthesia related complication.

#### **5.5 Recommendation**

Continuous monitoring of patients undergoing spinal Anaesthesia to post-recovery is essential for preventing and managing spinal Anaesthesia related complication.

Patients with compromised cardiopulmonary function should have baseline Arterial blood gas and pulmonary function done before spinal Anaesthesia

Intraoperative and postoperative shivering was observed to be the highest (76%) post-spinal Anaesthesia complication at the GARH. Mechanisms should be put in place to provide warmth and improve client's core temperature during surgery.

#### **5.6 Limitations of the study**

The sample size was small due to limited source of funding and duration of work. A larger size may be helpful to establish the relationship between pulmonary function changes and spinal Anaesthesia related complications

Comparative studies with participants with reduced lung function could have contributed to the results.

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## APPENDIX I

### TIMELINES/WORK SCHEDULE:

MONTHS ACTIVITIES	SEP	OCT	NOV.	DEC.	JAN	FEB	MARCH	APRIL	MAY	JUNE	JULY	AUG
Proposal												
Ethical clearance												
Pre-testing												
Literature review												
Data collection												
Data analysis												
Final report write-up												
Submission												

## APPENDIX II

### CONSENT FORM FOR PARTICIPANTS

Department of Physiology, School of Biomedical and Allied Health Sciences

University of Ghana

#### INFORMED WRITTEN CONSENT

This informed consent is to ask you to volunteer in a research study. The form will explain the study and it is important that you understand before deciding to participate. You may ask the persons in charge of the study who are listed on this page questions about the study at any time.

**This informed consent form has two parts:**

- **Information Sheet (To share information about the research with you)**
- **Certificate of Consent (for signatures if you agree to take part)**

#### PART ONE (1) INFORMATION SHEET

##### 1. WHAT IS THE TITLE OF THIS STUDY?

Pulmonary functional changes in Ghanaian patients undergoing spinal Anaesthesia

##### 2. WHO ARE THE PEOPLE IN CHARGE OF THE STUDY?

**MPHIL Student:** Melody Kwatemah Agyei-Fedieley; Department of Physiology, School of Biomedical and Allied Health Sciences, University of Ghana. Email: mkagyei-fedieley@st.ug.edu.gh. Tel. 233-244424137

**Principal supervisor:** Dr Bartholomew Dzudzor; Department of Medical Biochemistry, School of Biomedical and Allied Health Sciences, University of Ghana. Email: bartdzudzor7@gmail.com. Tel. 233-243716900

**Co-supervisor:** Dr Ebenezer Owusu Darkwa; Department of Anaesthesia, School of Medicine and Dentistry, College of Health Sciences, University Ghana. Email: eoddarquah@yahoo.co.uk. Tel. 233-244670149

### **3. WHAT IS THE PURPOSE OF THIS STUDY?**

Many patients who come for surgery go through a technique called spinal Anaesthesia so they will not feel pain before the cut of the surgeon's knife. This is done by giving an injection at the lower back. Though some patients do not have any underlining heart or breathing problems, they experience adverse complications related to the heart and the breathing system (cardiorespiratory complication) such as low blood pressure, slow and irregular pulse rate and sometimes difficulty in breathing. Although studies have shown that spinal Anaesthesia might affect the pathways of the heart and the blood vessels, the mechanism is not fully understood.

Our belief is that changes in the lung function (how the lung work in exchange of gases within the body) as a result of spinal Anaesthesia might be a contributory factor. Recent studies have shown that reduced lung function can predict sudden death in people with no related heart disease in the general population. The purpose of this study is to know the baseline of patient's lung function before spinal Anaesthesia. Also, to find out if there will be any changes in the patients' lung function after the spinal Anaesthesia compared to the baseline. Furthermore, if there are changes, to what extent will these changes in lung function lead to the development and/or severity of heart and breathing complications related to spinal Anaesthesia? This will be important to know so that Anaesthesia caregivers will identify those already with heart and breathing problems and give them treatments before spinal Anaesthesia to avoid these complications which might later lead to disabilities and long hospital stay.

### **4. WHAT IS THE PURPOSE OF COLLECTING THESE DATA FOR PULMONARY FUNCTION ANALYSIS?**

You are being asked to take part in this research study because you are undergoing spinal Anaesthesia for the surgery. The technique has an effect on the heart and the breathing system and may be associated with whether or not you may develop low blood pressure, slow and/ or irregular pulse and irregular breathing patterns. Studying the changes in pulmonary function in people undergoing spinal Anaesthesia may help us to better understand the extent to which these changes may be affected by spinal Anaesthesia and how the changes contribute to developing these adverse effects. You are taking part in this study by blowing out all the air you can into an

instrument called a spirometer after breathing in air as much as you can. You will also donate a small sample of your blood to test for gases you breathe in and out of your body. Participation is voluntary.

**5. WHO IS SPONSORING THIS STUDY?**

This study is being sponsored by myself and other funding bodies that may bring sponsorship later.

**6. WHO CAN BE IN THIS STUDY?**

You may participate in this study if you are undergoing spinal Anaesthesia for surgery. You do not need to have any known heart or breathing disease.

**7. HOW MANY PEOPLE WILL BE PARTICIPATING IN THIS STUDY?**

This study will involve approximately 70 people, ages 18 to 59years adults scheduled for elective surgery under spinal Anaesthesia at the Greater Accra Regional Hospital, Ridge

**8. WHAT IS THE PROCEDURE FOR DATA COLLECTION**

You will need to breathe in air as much as you can and blow all the air out as much as you can through a mouthpiece. Your nose will be closed with a nose piece so air comes out only through your mouth into the instrument you will hold in your hands. Trained doctors will insert a small rubber tube (cannula) into an artery in one of your arms once. We will take one (1) teaspoonful (1 ml) of blood from you at three different occasions throughout the entire study from the rubber tube.

**9. WHAT IS THE POTENTIAL RISK OR DISCOMFORT**

There is no risk with the procedure except for a little pain and discomfort when inserting the rubber tube. The pain can be described as a sharp ‘mosquito bite’ from the needle tip whiles inserting the cannula.

**10. WHAT ARE THE POTENTIAL BENEFITS TO ME OR OTHERS?**

It may help with your immediate management. Knowledge gained from the results of your participation in the study may additionally help in the management of others and the general population who come for surgery under spinal Anaesthesia.

**11. IS BEING IN THE STUDY VOLUNTARY?**

Being in the study is totally voluntary. Anyone who takes part in the study can decide to stop or withdraw at any stage or time. There will be no change in medical care given to anyone who decides to withdraw from the study. The researchers will destroy the samples obtained from anyone in the study if they are asked to do so.

**12. WHAT HAPPENS IF I DECIDE NOT TO PARTICIPATE OR WITHDRAW FROM THE STUDY?**

If you decide that you do not want your sample to be studied any longer, you can notify the investigators listed on the front of this form and your wish will be done.

**13. WHAT IS THE COST FOR BEING IN THE STUDY?**

There will be no charge to you for the tests involved in this study. It is absolutely free on your side. However, you are responsible for the cost of your surgery. Your National Health Insurance will cover part of your surgery and Anaesthesia and the difference will be paid by you.

**14. WILL PEOPLE BE PAID FOR BEING IN THE STUDY?**

You will not be paid for participating in this study. You will not receive either now or in the future financial benefits or any royalties which result from information obtained from this study.

**15. WILL I BE TOLD OF ANY NEW FINDINGS WHILE THE STUDY IS IN PROGRESS?**

Participants will be told of any significant new findings developed during the course of this study that may be of benefit to them.

**16. HOW WILL INFORMATION COLLECTED FROM AND ABOUT PEOPLE IN THE STUDY BE PROTECTED?**

All information will be maintained on a confidential basis. Your identity will be protected to the extent permitted by law. Understand that your samples will be coded with a unique identifying number and stored in a secure location. The confidentiality of any central computer record will be carefully guarded and no information by which you can be identified will be released or published.

The results of this research project may be presented at scientific meetings or in publications. However, your identity will not be disclosed in those presentations.

**17. WILL I HAVE ACCESS TO THE PULMONARY FUNCTION INFORMATION?**

You will be notified of your individual pulmonary function results but no results will appear in your medical records.

**18. HOW ELSE MIGHT THESE DATA BE USED?**

The data obtained in this study will be analyzed for baseline pulmonary function, any changes in pulmonary function after spinal Anaesthesia and its related adverse effects. The data will not be shared with other investigators. Your data will not be sold. It is possible that we may wish to contact you for further study. If you do not want to be contacted for further study, please indicate by checking the box below:

I do not want to be contacted

I do wish to be contacted

**19. WHO CAN I TALK TO ABOUT MY RIGHTS AS A STUDY PARTICIPANT?**

This proposal has been reviewed and approved by the Ethical and Protocol Review Committee of the University of Ghana and The Greater Accra Regional Hospital, Ridge which is a committee responsible to ensure that participants in this research are protected from harm.

If you have any questions concerning this study you may contact the Principal supervisor, Dr Bartholomew Dzudzor; Department of Medical Biochemistry, School of Biomedical and Allied Health Sciences, University of Ghana. Email: [bartdzudzor7@gmail.com](mailto:bartdzudzor7@gmail.com) Tel. 233-243716900, Co-supervisor, Dr Ebenezer Owusu Darkwa; Department of Anaesthesia, School of Medicine and Dentistry, College of Health Sciences, University Ghana. Email: [eoddarquah@yahoo.co.uk](mailto:eoddarquah@yahoo.co.uk). Tel. 233-244670149. You may also contact Dr Charles Hayfron-Benjamin; Anaesthesiologist, Consultant Pulmonologist, Department of Physiology, School of Biomedical and Allied Health Sciences, University of Ghana. Email: [charlesfhb1@gmail.com](mailto:charlesfhb1@gmail.com). Tel: 233-244080358 or the student, Melody Kwatemah Agyei- Fedieley Physiology Department, School of Biomedical and Allied Sciences, the University of Ghana on Tel. 0244424137

**Part II: CERTIFICATE OF CONSENT**

I.....

Voluntarily agree to participate in this study by having a spirometry test done and donating my blood sample. The risk and benefits have been fully explained/ translated to me. I am aware that every effort will be made to ensure my confidentiality.

..... **Date.....Place.....**

**(Signature/Thumbprint of participant)**

..... **Date..... Place.....**

**(Signature and full name of the investigator, Melody Kwatemah Agyei- Fedieley)**

**FOR ILLITERATE**

I.....

Acknowledge that the above-mentioned investigator signed this form in my presence

..... **Date.....place.....**

**(Signature of Witness)**

## APPENDIX III

Data collection instrument (Questionnaire)

### (Questionnaire is Interviewer Administered)

1.	STUDY ID				
		<b>Unique No.</b>			
2	DATE				

<b>PART A: CONSENT, INTERVIEW LANGUAGE NAME AND CONTACTS</b>				
2.	Consent has been read and obtained	1. <i>Yes</i>	2. <i>No</i>	<b><i>If NO, END</i></b>
3.	Phone number of participant (1)			
4.	Family Name			
5.	Other Nam(s)			
6.	Hospital Folder Number			
7.	Blood samples taken	1. <i>Yes</i>	2. <i>No</i>	<i>Ensure they are taken</i>
<b>PART B: SOCIODEMOGRAPHIC INFORMATION OF PARTICIPANT</b>				
8.	Gender	<i>Male</i>		<i>Female</i>
9.	Age (in years)			
10.	<b>Tribe (please tick) *</b>	1. <i>Akan</i>	2. <i>Ewe</i>	3. <i>Ga/Dangbe</i>
		4. <i>Mole/Dagomba</i>	5. <i>Mamprusi</i>	6. <i>Gruma</i>
		7. <i>Guan</i>	8. <i>others (please specify)</i>	
11.	Marital status (please tick)	1. <i>Never Married</i>	2. <i>Married</i>	3. <i>Separated</i>
		4. <i>Divorced</i>	5. <i>Widowed</i>	6. <i>Cohabiting</i>
12.	Highest level of education you have completed (please tick)	1. <i>No formal schooling</i>		4. <i>Tertiary</i>
		2. <i>Basic (Primary to JHS)</i>		5. <i>Post graduate degree</i>
		3. <i>Secondary school</i>		6. <i>Refused</i>
13.	Work Status (please tick) (Which of the ff best describes your main work status over the past 12 months?)	1. <i>Government employee</i>		2. <i>Non-government employee</i>
		3. <i>Self-employed</i>		4. <i>Student</i>
		5. <i>Homemaker / housewife</i>		6. <i>Retired</i>
		7. <i>Unemployed (able to work)</i>		8. <i>Unemployed (unable to work)</i>
		9. <i>Other (please specify)</i>		
14.	What is your occupation?			
15.	Previous Spinal Anaesthesia	Yes	No	Date(s) if yes
16.	Previous General Anaesthesia	Yes	No	Date(s) if yes
17.	Do you smoke tobacco products?	1. <i>Never Smoked</i>		2. <i>Currently smokes</i>
		3. <i>Previous smoked</i>		
18.	If you previously smoked, how long did you smoke for?			

19.	On average, how many sticks do you smoke each day?								
20.	Do you take alcohol	1. <i>Never drink alcohol</i>			2. <i>Occasional drinker</i>				
		3. <i>Regular drinker</i>							
<b>PART C: MEDICAL HISTORY</b>									
21.	Any known allergies	Yes	No	Specify if yes					
22.	Medical Conditions	Condition			Yes	No			
		Hypertension							
		Diabetes							
		Peptic ulcer disease / GERD							
		Angina or Previous MI							
		Convulsions or seizures							
		Others (please specify)							
23.	Current medications (drugs) (please list all)								
24.	HB Electrophoresis								
25.	Blood Group								
<b>PART D: ANTHROPOMETRIC MEASUREMENTS</b>									
26. HEIGHT IN CM		27. WEIGHT.....KG			28. BMI				
<b>PART E: SPINAL ANAESTHETIC PROCEDURE</b>									
29. Position		30. Needle Gauge			31. Interspace				
32. Level of sensory block		33. Modified Bromage Scale at 3 minutes							
34. Volume Of 0.5% Bupivacaine used									
<b>PART F: POST SPINAL EVENTS</b>									
<b>COMPLICATION / INTERVENTION</b>		<b>TICK IF PRESENT AT STATED TIMES IN MINUTES</b>							
		<5	5-<15	15-<30	30-<60	60-<90	90-<120	>120	After MBS=0
35.	Hypotension (SBP < 90 mmHg OR reduction in SBP>40mmHg from baseline)								
36.	Ephedrine (vasopressor) requirement (with dose)								
37.	Requirement for IVF to manage hypotension								
38.	Palpitations								
39.	Bradycardia								
40.	Atropine (antimuscarinic) requirement (with dose)								
41.	Other dysrhythmia (state type)								
42.	High block								
43.	Dyspnoea								
44.	SpO2<95%								

45.	Confusion								
46.	Headaches								
47.	Shivering								
48.	Nausea								
49.	Vomiting								
50.	Others (please specify)								
51.	Others (please specify)								
52.	Others (please specify)								

**Definition of Events and abbreviations**

- BRADYCARDIA: Heart rate less than 60 bpm
- DYSRHYTHMIA: New or worsening disturbance of heart rhythm requiring new treatment or a change in treatment
- MBS = Modified Bromage Score

\* Classification of tribe based on the classification by the Ghana Statistical Service and Ghana Health Service (Demographic and health survey) (Ghana Statistical Service, 2015)

## APPENDIX IV

Intraoperative

ID.....

Characteristics/intervention	Time(mins)									
	3	6	9	12	15	18	21	24	27	30
Blood pressure										
Pulse rate										
SPO <sub>2</sub>										
Atropine (dosage given)										
Ephedrine (dosage given)										
IV fluids										
Dyspnoea										
Headaches										
Shivering										
nausea										
vomiting										
others										

Post-surgery

Bromage score	Time(mins)										
	0	30	60	90	120	150	180	210	240	270	300
0											
1											
2											
3											

## APPENDIX V

### NATIVITY ASSESSMENT QUESTIONNAIRE

#### (QUESTIONNAIRE IS INTERVIEWER ADMINISTERED)

STUDY ID

Group      Unique No.

The following questions are aimed at confirming your Ghanaian nativity. Please answer the questions as accurately as you can.

A

1. **What is your mother's name?**
2. Where was she born (country of birth)?
3. Is/was she a Ghanaian?

4. **What is your father's name?**
5. Where was he born (country of birth)?
6. Is/was he a Ghanaian?

B

7. **What is your maternal grandmother's name?**
8. Where was she born?
9. Was she a Ghanaian?

**10. What is your paternal grandmother's name?**

11. Where was she born?
12. Was she a Ghanaian?

**13. What is your maternal grandfather's name?**

14. Where was he born?
15. Was he a Ghanaian?

**16. What is your paternal grandfather's name?**

17. Where was he born?

18. Was he a Ghanaian?

C

**19. What is your maternal great grandmother's name?**

20. Where was she born?

21. Was she a Ghanaian?

**22. What is your paternal great grandmother's name?**

23. Where was she born?

24. Was she a Ghanaian?

**25. What is your maternal great grandfather's name?**

26. Where was he born?

27. Was he a Ghanaian?

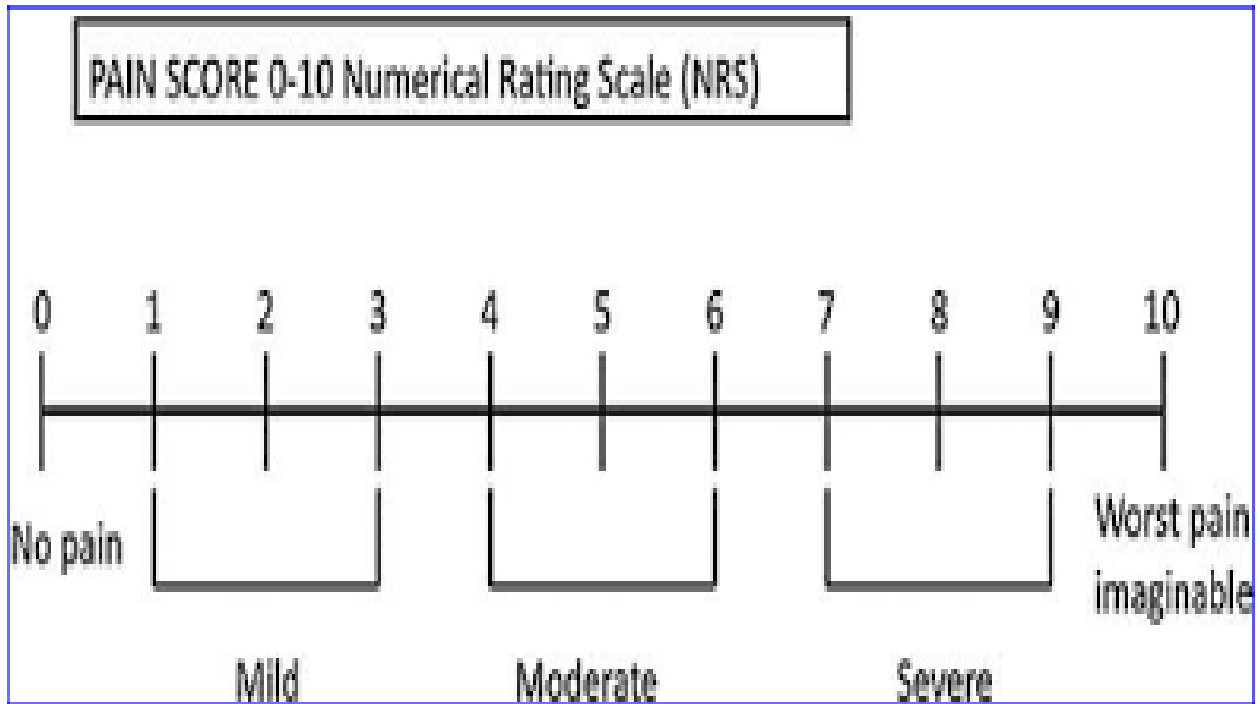
**28. What is your paternal great grandfather's name?**

29. Where was he born?

30. Was he a Ghanaian?

**APPENDIX VI**

ID .....



## APPENDIX VII



### UNIVERSITY OF GHANA COLLEGE OF HEALTH SCIENCES

ETHICAL AND PROTOCOL REVIEW COMMITTEE

Ref. No.: ..... EPRC/FEB/2019 .....

February 08, 2019

Mrs. Melody Kwatemah Agyei-Fedeleley  
Department of Physiology  
School of Biomedical and Allied Health Sciences  
Korle-Bu

#### ETHICAL CLEARANCE

Protocol Identification Number: *CHS-Et/M.6 – 5.17/2018-2019*

FWA: 000185779

IORG: 0005170

IRB: 00006220

The College of Health Sciences Ethical and Protocol Review Committee (EPRC) on February 08, 2019 reviewed and approved your re-submitted research protocol.

Title of Protocol: **"Pulmonary Functional Changes In Ghanaian Patients Undergoing Spinal Anaesthesia"**

Principal Investigator: **Mrs. Melody Kwatemah Agyei-Fedeleley**

This approval requires that you submit six-monthly review report(s) of the study to the Committee and a final full review report to the EPRC at the completion of the study. The Committee may observe, or cause to be observed, procedures and records of the study before, during and after implementation.

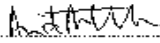
Please note that any significant modification(s) to this project/study must be submitted to the Committee for review and approval before its implementation.

You are required to report all serious adverse events related to this study to the EPRC within seven (7) days verbally and fourteen (14) days in writing.

As part of the review process, it is the Committee's duty to review the ethical aspects of any manuscript that may be produced from this study. You will therefore be required to furnish the Committee with any manuscript for publication.

**This ethical clearance is valid till February 10, 2020.**

Please always quote the protocol identification number in all future correspondence in relation to this protocol.

Signed: 

**Professor Andrew Anthony Adjei**  
Chair, Ethical and Protocol Review Committee

cc: Provost, CHS  
Dean, SBAHS  
Head, Department of Physiology

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• P. O. Box 6802, Korle Bu, Accra, Ghana. • Telephone: +233 (0) 302 665103/4 • Fax: +233 (0) 302 660762  
• Email: [edmir.chs@ug.edu.gh](mailto:edmir.chs@ug.edu.gh) / [provost.chs@ug.edu.gh](mailto:provost.chs@ug.edu.gh) • Website: [www.ug.edu.gh](http://www.ug.edu.gh)