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A randomised controlled trial comparing haemodynamic stability in elderly patients undergoing spinal anaesthesia at l5,s1 versus spinal anaesthesia at l3,4 at the Aga Khan University hospital, Nairobi

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A RANDOMISED CONTROLLED TRIAL COMPARING HAEMODYNAMIC STABILITY IN ELDERLY PATIENTS UNDERGOING SPINAL ANAESTHESIA AT L5,S1 VERSUS SPINAL ANAESTHESIA AT L3,4AT THE AGA KHAN UNIVERSITY HOSPITAL, NAIROBI .

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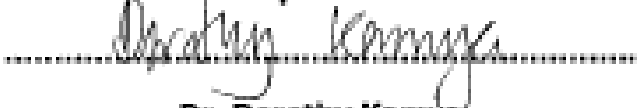

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ABSTRACT

Background

Spinal anaesthesia is a routinely used anaesthetic technique for elderly patients undergoing operations involving the lower limbs, lower abdomen, pelvis and the perineum. Spinal anaesthesia has several advantages over general anaesthesia and these include stable haemodynamic variables, less blood loss, less post operative pain, faster recovery time and less post operative confusion. However, despite these advantages, the sympathetic blockade induced by spinal anaesthesia can result in hypotension, bradycardia, dysrhythmias and cardiac arrests.

Conventionally, spinal anaesthesia is performed at the level of L3,4 interspace; with a reported incidence of hypotension in the elderly ranging between 65% and 69%. A possible strategy for reducing spinal induced hypotension would be to minimize the peak block height to as low as possible for the planned procedure.

The purpose of this study was to investigate the decrease in mean arterial pressures and change heart rates from baseline values (haemodynamic stability) of elderly patients undergoing spinal anaesthesia performed at the level of L5, S1 compared to the conventional level at the L3, 4 interspace.

Objective

To determine the difference in haemodynamic stability between elderly patients undergoing spinal anaesthesia at L5, S1 interspace compared to elderly patients undergoing spinal anaesthesia at L3, 4.

Study design

A randomized single blinded controlled trial

Methods

Thirty two elderly patients scheduled for lower limb or pelvic surgery under spinal anaesthesia were randomized into 2 groups (control group and intervention group) using a computer generated table of numbers.

Control group; received 2.5 mls 0.5% hyperbaric bupivacaine injected intrathecally at the L3, 4 interspace

Intervention group; 2.5mls 0.5% hyperbaric bupivacaine injected intrathecally at the L5, S1 interspace

Results

The two groups had similar baseline characteristics in age, sex, body mass index and use of anti-hypertensive medications. There was 68.75% proportion of hypotension in the control group and 75% in the intervention group. The difference was not found to be statistically significant (p= 0.694). During the study period, there were 106 episodes of hypotension, out of which, 65 were in the control group and 41 in the intervention group (p=0.004). This difference was statistically significant.Linear regression analysis of the decrease in mean arterial pressures (MAP) showed a higher decrease in MAP in the control group (p 0.018). There were more crystalloids used in the control group (1006mls ± 374) than in the intervention group (606mls ±211) with a p< 0.0001. There was no difference in the amounts of vasopressors used between the two groups (p=0.288).There was no difference in the change in heart rates,conversion to general anaesthesia, use of supplementary intravenous fentanyl and the peak maximum block level achieved. The time to peak maximum level was 9.06min and 13.07min in the control group and intervention groups, respectively (p<0.0001).

Conclusion

Among this population, there was no difference in the proportion of those with hypotension between the elderly patients who received their spinal anaesthesia at L3,4 and those who received spinal anaesthesia at L5,S1. There were significantly less episodes of hypotension in the intervention group. It took a longer time to achieve a maximum peak sensory block in the intervention group. Performing spinal anaesthesia at the level of L5,S1 was found to provide an adequate sensory block for a wide range of pelvic, perineal and lower limb surgeries.

The study was registered under Pan African Clinical Trials Registration number PATCR 201109000311318

LIST OF ABBREVIATIONS

AKUH, N- Aga Khan University Hospital, Nairobi

BMI-body mass index

BP- Blood pressure

cm- centimeters

CSF –cerebral spinal fluid

GA- general anaesthesia HR-heart rate

Kg-kilogrammes

MAP-mean arterial pressures

min-minutes

mmHg –millimetres of mercury

SA –Spinal anaesthesia

SD-standard deviation

TURP-Trans-urethral resection of the prostate

PREFACE

The theoretical framework of this study was two-fold. It was based primarily on the scientific premise that hypotension secondary to spinal anaesthesia is as a result of sympathetic outflow blockade and that the less the blockade,the less the haemodynamic disturbance. Secondarily, anecdotal observations by Dr T Sharif (consultant anaesthesiologist, AKUH,N) that those patients who received spinal anaesthesia at L5,S1 had less haemodynamic disturbances than those who received their spinal anaesthesia at the conventional level of L3,4.
Based on these, this randomised controlled study to compare the haemodynamic variables between elderly patients who received spinal anaesthesia at L3,4 and those who received spinal anaesthesia at L5,S1 was conceptualized.

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Thank you all.

DECLARATION

I declare that this dissertation does not incorporate without acknowledgement any material previously submitted for a degree or diploma in any university, and that to the best of my knowledge it does not contain any material previously published or written by another person except where due reference have been made in the text.

The editorial assistance provided to me has in no way added to the substance of my dissertation, which is the product of my own research endeavors.

(Signature of candidate)

25.05.12.

(Date)

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1.0 INTRODUCTION

Spinal anesthesia (SA) consists of the temporary interruption of nerve transmission within the subarachnoid space produced by injection of a local anesthetic solution into cerebrospinal fluid (CSF).

SA is a routinely used anaesthetic technique for operations involving the lower limbs, lower abdomen,pelvic and perineal surgeries(1–3). An increasing proportion ofthe patients undergoing these surgical procedures are the elderly(4). Age related changes in physiology and pharmacology can affect every aspect of peri-operative care (5).

The use of spinal anaesthesia is increasing in popularity compared to general anaesthesia(1,2,6). Spinal anesthesia has many potential advantages over general anesthesia which include; stable haemodynamic variables, less blood loss, less post operative pain, faster recovery time, less post operative deep venous thrombosis and less post operative confusion in the elderly age group, compared to general anesthesia (GA) (3,7–9).
However, along with the analgesia, anesthesia and motor blockade, spinal anesthesia also induces a sympathetic block that maycause hypotension, bradycardia, nausea, vomiting, dysrhythmias and rarely, cardiac arrest (10–13).

2.0 SPINAL ANAESTHESIA

2.1 Physiology of spinal anaesthesia

SA consists of the temporary disruption of nerve transmission within the subarachnoid space produced by injection of a local anaesthetic solution into cerebrospinal fluid(CSF) (14).

During spinal anesthesia, local anesthetics are found both in nerve roots and within the substance of the spinal cord. However, the major cause of loss of sensation and muscle relaxation during spinal anesthesia is the presence of local anesthetics in spinal nerve roots and in dorsal root ganglia, not within the spinal cord. The concentration of local anaesthetics in nerve roots is a function of distance from the site of highest concentration of local anesthetic in CSF(15,16).This, combined with the fact that different types of nerve fibers differ in their sensitivities to the blocking effects of local anesthetics, gives rise to zones of differential blockade of great clinical and physiologic importance. These zones of differential blockade are most apparent and most readily measured above the site of highest concentration of local anesthetic in CSF. During spinal anesthesia the concentration of local anaesthetic in CSF decreases in cephalad direction until it becomes so low that it is sufficient to block only those nerve fibers in the subarachnoid space that are most sensitive to local anesthetics. These are the preganglionic sympathetic nerves (B fibres). This decrease in local anesthetic concentration gives rise to a zone of differential sympathetic denervation as measured by loss of cold temperature discrimination (C fibres) during spinal anesthesia that averages two spinal segments above the level of pinprick sensory blockade (A-delta fibres). Because the most cephalad preganglionic sympathetic fiber comes off the spinal cord at the level of T1, the two-segment zone of differential sympathetic block means that a sensory level at T3 is associated with total preganglionic sympathetic (B fibres) denervation. This zone of differential blockade remains constant in extent during maintenance and regression of the level of spinal anesthesia as the anesthesia wears off from above downwards. Furthermore, the spinal segmental level at which the cutaneous sense of cold is lost lies about two segments above the level of pinprick anesthesia, which in turn lies about one segment above the level of anesthesia to light touch (8). Therefore, testing for the level of loss of the sensation of light touch would be the best sensory modality to test for the level of block adequate for surgery(14,16). To test level of sympathetic denervation and thus the

potential for changes in cardiovascular function during spinal anesthesia, in theory one should test for the level of loss of temperature discrimination(14).

Somatic sensory afferent fibers are in general also more sensitive to local anesthesia than somatic motor fibers. This creates another zone of differential blockade during spinal anesthesia, a level of somatic motor blockade that lies below the level of somatic sensory blockade. This zone of differential blockade also averages two spinal segments below pinprick level. It determines the extent of surgical relaxation of the anterior abdominal wall as well as the effect of spinal anesthesia on the respiratory muscles, neither of which is the same as the level of surgical anesthesia nor the extent of sympathetic denervation and thus the extent of physiologic trespass during spinal anesthesia(14,15). This explains the effect of spinal anesthesia on the cardiovascular system –hypotension, bradycardia, cardiac arrest - due to the sympathetic denervation effects which are far above the sensory block (14,15,17,18).

2.2 Cardiovascular effects of SA

Hypotension during SA results primarily from blockade of the sympathetic nervous system, which causes a decrease in systemic vascular resistance and cardiac output; where,

Blood pressure = systemic vascular resistance x cardiac output.
Thus, systemic vascular resistance decreases as a result of a reduction in the
sympathetic tone of the arterial circulation which causes peripheral arterial vasodilatation, the extent of which depends on the number of spinal segments blocked. Sympathetic block also causes venodilation with pooling of blood in the large veins of the abdomen and lower limbs, which causes a reduction in preload to the heart and a decrease in stroke volume. However, the heart is able to compensate by increasing heart rate and contractility. Hence, it is only when the decrease in preload is large and the heart can no longer compensate, that the cardiac output decreases and thus hypotension occurs .When the block is lower than T4, compensatory vasoconstriction in the upper extremities moderates the pressure drop. When the block is sufficiently high, the cardio-acceleratory nerves to the heart (TI-T4) also become blocked. This decreases cardiac output by reducing heart rate and contractility (14,17,18).

In elderly patients, a decrease in adrenoceptor responsiveness results in increased adrenomedullary output and plasma catecholamine concentration(5). Therefore, the elderly have an increased resting sympathetic nervous system activity and associated catecholamine (norepinephrine) release at the nerve terminals. Furthermore, their physiological reserve is reduced(5).The sympathetic block secondary to SA is therefore more likely to lead to severe hypotension in the elderly patient. The most common complications of SA are hypotension with an incidence in the elderly of between 25 and 69%; nausea (18%); bradycardia (13%); vomiting (7%) and dysrhythmias (2%)(10,19,20).

The factors associated with increased risk of hypotension during spinal anesthesia include; spinal puncture at or above the L2,3 interspace, sensory block height higher than T6, history of hypertension , age more than 40 years, baseline systolic blood pressures less than 120mmHg and combination of spinal and general anesthesia (10,21).

The elderly are at an increased risk of developing long term complications from hypotension because they have a reduced physiological reserve and an increased incidence of systemic diseases(19). The incidence of cardiovascular side effects increase as the block heights increase from the lower thoracic levels. A possible strategy for reducing these side effects would be to minimize the peak block height to as low as possible for the planned surgical procedure. However, attempts to minimize peak block height will have to be balanced against the risk of producing anesthesia that is insufficient for surgery(10,21).

This study aimed to investigate the haemodynamic stability of elderly patients undergoing surgical procedures under spinal anesthesia performed at the level of L5, S1 compared to the conventional level at the L3, 4 interspace.

2.3 Anatomical changes of the spine in the elderly

It can be difficult to perform neuraxial anesthesia in the elderly age group. Positioning patients for regional anesthetic techniques becomes increasingly difficult with age(22). The anatomic configuration of the lumbar and thoracic spine also changes. Elderly individuals often have dorsal kyphosis and a tendency to flex the hips and knees because of osteoarthritic changes and cartilage calcification. In advanced age with degenerative disk and joint changes, distortion and compression of the epidural space are common. The ligamentumflavum probably changes into a form that is easily ossified. Attempts to accomplish dural puncture for spinal anesthesia are often unsuccessful because needle placement and advancement may not be easy, especially through calcified ligaments. Similarly, the presence of osteophytes decreases the size of the intervertebral foramina, limiting the access to the subarachnoid space. There are no easy solutions to the technical difficulties that these anatomic changes present.

The largest intervertebral foramina are in the L5, S1 interspace; this anatomic characteristic can be used clinically to gain access to the epidural or subarachnoid space in patients with severe osteoarthritis and ossified ligaments(14,22).Though the widest interspace, it is often inaccessible from the midline because of the acute downward orientation of the L5 spinous process. In Taylor's approach, the spinal needle is passed from a point 1cm caudad and 1cm medial to the posterior superior iliac spine and advanced cephalad at a 55 degree angle with medial orientation based on the width of the sacrum. A lateral approach of the needle to the epidural and subarachnoid space may avoid both the increased calcification in the midline and the tendency of the dorsal vertebrae to impact on one another.The Taylor approach is also useful because it is minimally dependent on patient flexion for successful passage of the needle into the subarachnoid space(14,22).

3.0 LITERATURE REVIEW

3.1 General Anesthesia Versus Spinal Anesthesia

Many studies have been conducted to compare the peri operative outcomes of patients undergoing surgery under general anesthesia (GA) with spinal anesthesia (SA).

In a systematic review conducted by Rodgers et al, 141 randomised and quasi randomized trials(9559 patients) involving a wide range of surgical procedures to obtain estimates of the effects of neuraxial blockade with epidural or spinal anesthesia compared to general anesthesia on postoperative morbidity and mortality(3). The review showed that neuraxial blockade reduced mortality by one third, reduced the risk of deep vein thrombosis, pulmonary embolism, transfusion requirements, pneumonia, respiratory depression, myocardial infarction and renal failure(3). However, this systematic review involved both randomized and quasi randomized trials and a wide range of surgeries. Therefore, their findings are open to question due to the heterogeneity of the population. They also reviewed all trials as long as they involved central neuroaxial blockade irrespective of their primary aims or concomitant use of GA.

Urwin and coworkers conducted a metaanalysis of 15 randomized and quasi randomized trials involving 2162 patients undergoing hip fracture surgery under either general anesthesia or spinal anesthesia(23). They found reduced one month mortality, reduced incidence of deep venous thrombosis and a tendency towards a lower incidence of myocardial infarction, confusion and post operative hypoxia in the spinal anesthesia group. They also found reduced cerebral vascular accidents and intraoperative hypotension in the general anesthesia patients(23).

In another metaanalysis comparing neuroaxial blockade with general anesthesia in patients undergoing elective total hip replacement, Mauermann et al demonstrated significant reduction in deep venous thrombosis and pulmonary embolism, reduced intraoperative blood loss and transfusion requirements and reduced operative time in those patients under neuroaxial blockade. This metaanalysis involved ten randomized controlled trials(24).

There have been several randomized controlled trials comparing GA and SA for patients undergoing prostate surgery.Salonia et al evaluated intra and post operative outcomes in patients undergoing GA versus SA for radical retro pubic prostatectomy(7). They demonstrated less blood loss, less post operative pain, earlier ambulation and good haemodynamic and respiratory safety profile in the SA group. Dobson et alconducted a randomized controlled trial on patients undergoing trans-urethral resection of the prostate (TURP) comparing haemodynamic stability in those under GA versus those under SA(9). They concluded that SA results in more stable haemodynamic variables compared to GA. Chung et al compared mental function during peri-operative period in 44 elderly patients (above 60 years) undergoing either GA or SA for TURP or pelvic floor surgery(8). They demonstrated that maintenance of mental function following SA was better; with significant impairment of cognitive function up to three days post operatively in elderly patients following GA.

Based on the above evidence(3,7–9,23,24) there is a general consensus that for urological surgeries, orthopaedic, vascular and other surgeries on the lower abdomen and lower limbs, central neuroaxial blocks (which include SA) confer several advantages over GA with less morbidity and mortality, especially in the elderly population. These advantages include; stable haemodynamic variables, less respiratory complications less blood loss and transfusion requirements, less post operative pain, early mobility with fewer events of deep venous thrombosis and pulmonary embolism (3,7–9,23,24).

3.2 Incidence and risk factors for hypotension secondary to spinal anesthesia (SA)

Although SA has always been considered a safe technique for anesthesia, it is not without risks and side effects.Hypotension, nausea, bradycardia , vomiting,dysrhythmias and rarely, cardiac arrests have been known to occur (10–12,17,19,20,25,26).

Maintenance of haemodynamic stability during SA is the subject of an increasing number of trials. In a prospective study specifically looking for incidence and risk factors for side effects of SA, Carpenter et al defined hypotension as a systolic blood pressure of less than 90mmHg and found a 33% incidence of hypotension in 314 patients(10). They demonstrated a correlation of

hypotension and nausea, bradycardia and vomiting.They showed that variables conferring increased odds of developing hypotension were ; spinal puncture at or above the L2, 3 interspace, peak block height higher than T5, age more than 40years, baseline systolic blood pressure less than 120mmHg and combination of SA and GA(10).

In a similar study analyzing incidence and risk factors for hypotension after SA, Hartmann and co-workers found a decrease of mean arterial pressure (MAP) requiring therapeutic intervention in 50.8% patients(21). There was decrease in MAP by 20-30% in 50.4% of the patients, and decrease by more than 30% in 8.2% of the cases. The following factors were identified as independent factors for relevant hypotension: chronic alcohol consumption, pre-operative history of hypertension, sensory block height higher than T6, urgency of surgery and a high body mass index (BMI).

The common risk factor for hypotension in most of these studies was the peak sensory block. The higher the sensory block, the more the thoraco-lumbar sympathetic chain blockade; the more the incidence and severity of the hypotension and the need for vasopressors(10,19,26).

In a prospective study to evaluate the sensitivity and specificity of various predictors hypotension during onset of hypotension in elderly patients (aged more than 60years), Meyhoff et al found an incidence of hypotension of 65%(3).Critchley and associatesin another prospective study on haemodynamic effects of SA on the elderly, found an incidence of hypotension of 69% (19).

Pitkanen and associates found a statistically significant correlation between age and cephalad spread of anesthesia(27). They found that the peak sensory block was higher in the older patients for the same volume of local anaesthetic. They also found that in patients in the older decades in life, the decrease in blood pressure was correlated to the block height. If, however, age was associated with progressive decrease in CSF volume, this might mean that this data could be applied to situations where the elderly patient is undergoing SA to either reduce the dose or perform it at a lower level (27).

3.3 Prevention of hypotension induced by spinal anaesthesia

Most of the published work on prevention and treatment of hypotension secondary to SA has involved obstetric patients(28).There has been less attention paid to the effect of various means of prevention of hypotension on the elderly despite their greater vulnerability to decompensation from rapid fluid shifts, haemodilution and haemodynamic instability.

Buggy et al conducted a study to compare the effects of prehydration with colloids (500mls), crystalloids (500mls) and no prehydration and concluded that in elderly patients undergoing elective procedures, withholding prehydration was not associated with a greater degree of hypotension or vasopressor therapy(25). In contrast, Baraka et al demonstrated that prophylactic administration of colloid at 7ml/kg was more effective than crystalloid 7ml/kg at attenuating SA induced hypotension in patients undergoing TURP(29). Kati et al found that 7.5% hypertonic saline was as good as normal saline for the same amount of sodium load for prehydration before spinal anaesthetic(30). Other studies have been conducted to investigate the effects of prophylactic crystalloid and colloid loading alone , and in combination with various vasopressors including ephedrine, phenylephrine, metaraminol, methoxamine, dihydroergotamine among others (18,31–36). It was found that combination of fluids and vasopressor as the best prophylaxis against hypotension.

There seems to be no consensus on prevention of hypotension secondary to SA in the elderly population. There has not been much publication on using a lower site of injection to maintain haemodynamic stability by limiting the level of block. Very few studies have reported SA at the level of L5, S1 interspace. Case reports of SA for caesarian section in patients with previous corrective spine surgery being inserted at the level of L5, S1 have been reported (37). In these reports, the blood pressures remained stable, with no need for vasopressors, yet with an adequate block for a caesarian section. There is also one case report of SA for neck of femur fracture repair in an 86 year old with previous spinal surgery at L1 to L4. The paramedian approach (Taylor technique) of identifying the L5, S1 interspace was used successfully. The patient had a sensory level of T10 which was adequate for the surgery and his haemodynamic variables remained stable(38).

3.4 Effect of site of injection on haemodynamic stability

There have been few studies demonstrating the effect of level of spinal injection on the height of block(39–41).However, there are no studies cited that have demonstrated the relation between the level of spinal injection and the haemodynamic stability of the patients; nor the relation between the level of the spinal block and the haemodynamic stability. The studies that have investigated the effect lumbar interspace powered their studies to detect a difference in the level of sensory block and analgesia and only reported blood pressure changes in the results.

In a randomized trial, Veering et al investigated the effect of site of injection on spread of analgesia in elderly patients (39). They randomized elderly male patients (ages between 68 to 87 years) undergoing minor urological surgery to receive spinal anaesthetic at either L3, 4 or L4, 5 interspace. The lumbar interspace was determined by palpation to confirm the position of L4 in relation to the iliac crests. They concluded that there was no significant difference in the time to maximum cephalad spread of analgesia, maximum degree of motor block or haemodynamic changes between the two groups. The study was powered to detect a difference of 2 segments (of analgesia) between the two groups. They recorded a maximum decrease in systolic blood pressures as a median of 23% (95%C.I 18%-29%) in the L3, 4 group and 18% (95% C.I 16%-22%) in the L4, 5 group. However, it is well known that lumbar interspaces may be easily misidentified by palpation and use of the line joining the two iliac crests (Tuffier's line)(42,43). More definite identification of the correct interspaces would have required X ray marking.

In a study using 3mls plain 0.5% bupivacaine, Becker et al investigated the influence of level of injection on sensory anesthesia(40). They randomized 20 patients to receive SA at either L2, 3 or L4, 5 interspace. Identification of the interspaces was made using palpation using Tuffier's line. The study was powered to detect a difference in maximum level of sensory anesthesia of 2 segments as significant. They found a 1 (one) segment difference between the two groups which they found to be statistically and clinically insignificant. According to the results 3 patients (30%) in the L3, 4 group required ephedrine compared to 1 patient (10%) in the L4, 5 group(40).

In a similarly designed study, Olsen and coworkers compared the effects of the same volume and dose of plain bupivacaine injected at the level of L2,3 or L4,5 interspace(41). They found no significant differences in onset time, extent and duration of analgesia or motor block in the two groups. They also reported a decrease of 8% in mean arterial pressures (MAP) in both groups.

Therefore, from the studies conducted on the effects of site of injection on level of analgesia(39–41), the results could be extrapolated to expect a clinically significant difference in level of analgesia and in the decrease in blood pressures if we compared spinal anesthesia for elderly patients at the level of L3,4 interspace with those of spinal anesthesia at L5,S1 interspace .

3.5Identification of Lumbar Interspaces

Palpation is used by anaesthesiologists to identify a suitable vertebral level for spinal anesthesia. There is no element of self correction in this process as the selected site is not usually confirmed radiographically. Therefore, an experienced doctor may not necessarily be able to identify a particular vertebral interspace more accurately than a beginner(43). In this respect, pain specialists who regularly use radiographic control of needle placement may have advantage over the average clinical anaesthesiologist(42).

In a study conducted to determine whether anaesthesiologists are able to identify correctly a marked lumbar interspace, Broadbent and colleagues recruited 100 subjects and involved 4 senior anaesthesiologists(43). For each patient, 2 anaesthesiologists attempted to identify lumbar interspaces by palpation of spinous processes and iliac crests and placed a marker; an MRI scan was then performed to identify the interspace marked. The marker was one space higher than assumed in 51% of cases; 2 spaces higher in 15.5%; 3 spaces higher in 1% and in 0.5%cases the marker was 4 spaces higher. They found an accuracy of 29% in palpation. Accuracy was not improved by use of sitting position and was worsened by obesity. Furness et al corroborated the inaccuracy and showed that clinical identification by palpation was 30%

accurate(44). These studies demonstrate that anaesthesiologists cannot reliably identify a particular interspace by palpation (43,44).

Further, Chakraverty et al carried out a study aimed to assess the accuracy and agreement between examiners when attempts to identify L5, S1
interspace by use of passive motion testing. They found the true level accurate in 55% to 57% of cases as confirmed by fluoroscopic imaging. They concluded that even segmental passive motion testing was an unreliable method of identification of the correct spinal level.(45)

Render et al reviewed 163 postero-anterior lumbar X ray films in a study to identify the accuracy with which the iliac crest can be used as a marker of lumbar spine level. They identified the iliac crests and drew a horizontal line joining their highest points (Tuffier's line); and the spinal level marking the intersection with the Tuffier's line was determined. This point of intersection coincided with L3,4 interspace in 3.7%;L4 spine in 48.5%;L4,5 interspace 30.1 %;L5 spine in 14.1%;L5,S1 in 3.7%. They concluded that the Tuffier's line was an unreliable landmark of vertebral interspaces(46).

The use of ultrasound imaging for identification of lumbar intervertebral level has been investigated and found to have an accuracy of 71% and 76% in studies conducted to compare ultrasound imaging with X ray and MRI imaging respectively(44,47)although ultrasound imaging is quick to perform ,the image quality can vary markedly between patients and is operator dependent, requiring technical skill of interpretation of lumbar spines and interspaces.(44) Ultrasound imaging for identification of lumbar intervertebral level does not account for possibility of fused or extra vertebrae(48).

Therefore, only the use of X ray imaging or MRI would give 100% accuracy in identification of vertebral interspaces.MRI is expensive, bulky and inconvenient to use for purposes of placing a spinal or epidural needle in the correct interspace. In comparison, the use of X rays, through an image intensifier is convenient, inexpensive and portable into the operating theatres yet confers the accuracy we would need to confirm the interspaces.

4.0 JUSTIFICATION OF THE STUDY

Functional reserve and ability to compensate for physiological stresses are reduced in the elderly (5).The elderly also have an increased incidence of co-morbidities which include cardiovascular and pulmonary diseases. If performing spinal anaesthesia (SA)for elderly patients at the level of L5, S1 is found to result in an adequate block whilst providing haemodynamic stability; this shall be a step forward in making SA safer for these patients in whom cardiovascular stability is critical in reducing morbidity and mortality.

Most of the published studies report performing the SA at the L2, 3 or L3, 4 interspaces and a few at the L4, 5 interspace (49–51). Conventionally, SA is associated with a high incidence hypotension and cardiovascular instability in the elderly age group.The incidence of hypotension secondary to SA in elderly patients ranges from 65% to 69% (19,20).

The understanding that it is important to limit the distribution of spinal block especially in the elderly has been demonstrated to reduce adverse haemodynamic and pulmonary effects in such patients .There have been efforts to use lower doses of local anaesthetic (50); or to use a low dose of local anaesthetic in combination with opioids to improve the sensory block in the elderly patients while avoiding hypotension.(52) In as much as lower doses are associated with better cardiovascular stability, they have been associated with less than adequate block for pelvic surgeries liketransurethral resection of the prostate (TURP)(50).

There are very few studies that have performed SA at the level of L5, S1 interspace. Case reports of SA for caesarean section in patients with previous corrective spine surgery being inserted successfully at the level of L5, S1 have been reported (37).

The use of an X ray image intensifier would overcome the technical challenge of identifying the interspace accurately by clinical palpation(40; 42; 43; 44).

Based on the above literature, we hypothesized that performing the SA in elderly patients at L5,S1 would result in minimum disruption of haemodynamic variables compared to the conventional spinal anesthesia at a higher level.

5.0 Research question

Does spinal anesthesia (SA) in elderly patients at the level of L5, S1 interspace result in less haemodynamic disturbance, as evidenced by proportions ofhypotension , compared to SA at L3,4 interspace?

5.1 Alternate hypothesis

There is a difference in the proportion of hypotension among elderly patients who have undergone spinal anaesthesia at the level of L3, 4 interspace compared to those who have undergone spinal anaesthesia at the level L5, S1 interspace.

6.0 OBJECTIVES

6.1 Primary objective

To determine the difference in proportion of hypotension between an intervention group of elderly patients undergoing spinal anaesthesia at L5, S1 interspace compared to a control group undergoing spinal anaesthesia at L3, 4.

6.2 Secondary objectives

1. To describe the difference in heart rate reduction in patients undergoing spinal anaesthesia at the level of L5, S1 interspace compared to spinal anaesthesia at L3, 4.

2. To compare the use of supplementary analgesia and conversion rate to general anaesthesia (GA) between the two groups.

3. To determine the level of sensory block in patients undergoing spinal anaesthesia at the level of L5, S1.

7.0 METHODOLOGY

7.1 Study design

Randomized single blinded controlled trial

7.2 Study site

The study was conducted at the Aga Khan University Hospital, Nairobi. The Aga Khan University Hospital, Nairobi (AKUH, N) is a 254-bed private not-for-profit institution that provides tertiary and secondary level health care services. It is a hospital run by the Aga Khan University, East Africa.

The hospital serves the residents of Nairobi and also receives referrals from other parts of the country and the continent. It is a teaching hospital that offers courses in post graduate medical education and advanced nursing.

The AKUH, N has five operating theatres .There were approximately 8,000 surgical procedures performed in 2011.

7.3 Study population

7.3.1 Reference population

The target population included all elderly patients, aged 60years and above, admitted for lower limb and pelvic surgeries at the Aga Khan University Hospital operating theatres.

7.3.2 Sample population

The sample population included all elderly ASA I to III patients scheduled for surgical procedures that were amenable for spinal anaesthesia(lower limb and pelvic surgeries)in the period between October 2011 and March 2012.

7.3.3 Study population

This comprised all elderly patients undergoing SA for lower limb and pelvic surgeries who had given consent for the study.

7.4 ELIGIBILITY CRITERIA

7.4.1 Inclusion criteria

All elderly ASA I –III patients scheduled to undergo lower limb and pelvic surgeries.

7.4.2 Exclusion criteria

1. Patient refusal to participate in the study
2. Contraindication to spinal anesthesia
    a. Coagulopathy
    b. Haemodynamically unstable patient
    c. Increased intracranial pressure
    d. Sepsis
    e. Infection at the puncture site
3. Severe cardiac disease graded as NYHA III –IV

7.5 SAMPLE SIZE DETERMINATION

The sample size was calculated using a STATA 11(StrataCorp, USA).A sample size of 32 patients was determined as sufficient to demonstrate a 59% difference in the prevalence of hypotension between elderly patients who receive spinal anaesthesia at the level of L3, 4 and those who receive spinal anaesthesia at the level of L5, S1 at the Aga Khan University Hospital. The study was powered at 90%. Type 1 error was set at 0.05. Previous studies show 69% incidence of hypotension when spinal anaesthesia was performed at L3, 4. (19)

The prevalence of hypotension in the intervention arm was determined from case series and operations performed using spinal anaesthesia at L5, S1 (case series)was found to be 10%.

The formula used is by the program is based on a chi test with Yate's continuity correction described by Fleiss, Levin and Paik(53,54).

$$n_1 = \frac{n'}{4}\left[1 + \left\{1 + \frac{2(r+1)}{n'r\,|\,p_1 - p_2|}\right\}^{1/2}\right]^2$$

$$n_2 = rn_1$$

Where;

$$n' = \frac{\left[z_{1-\alpha/2}\left\{(r+1)\overline{pq}\right\}^{1/2} + z_{1-\beta}\left(rp_1q_1 + p_2q_2\right)^{1/2}\right]^2}{r(p_1 - p_2)^2}$$

$$\text{and } \overline{p} = (p_1 + rp_2)/(r+1) \text{ and } \overline{q} = 1 - \overline{p}$$

α is the significance level, 1-β is the power, $z_{1-\alpha/2}$ is the $(1-\alpha/2)$ quantile of the normal distribution, and r=n2/n1 which is the ratio of sample sizes.

p1= 69% {incidence of hypotension when spinal anaesthesia was performed at L3, 4 (19) }

p2=10% {incidence of hypotension when spinal anaesthesia is performed at L5, S1 in case series was taken as 10% (n=10)}[1]

n' =16 patients in each arm

Total =32 patients

[1] Anecdotal case series 2011
Strategies to reduce the cardiovascular side effects of spinal anaesthesia by minimising the block height by performing the procedure at L5,S1 . T Sharif , Aga Khan University Hospital, Nairobi.

7.6 PROCEDURES

7.6.1 Recruitment

The study participants were recruited from the preoperative anesthesia clinic (pre anaesthetic review) and the inpatient surgical wards. All potential participants received oral and written explanation (appendix 1) on the purpose and procedure of the study from the principal investigator and a written signed informed consent sought (appendix 2). The patients who gave written informed consent were then enrolled into the study and given serial numbers.

7.6.2 Randomization

Simple randomization was used. Using a computer program, the principal investigatorgenerated a random sequence of numbers. Each of the random numbers was sequentially assigned to either;
Control group; 2.5 mls 0.5% hyperbaric bupivacaine injected intrathecally at the L3, 4 interspace

Intervention group; 2.5mls 0.5% hyperbaric bupivacaine injected intrathecally at the L5, S1 interspace

7.6.3 Anaesthetic procedure

The study was undertaken at the Aga Khan University Hospital Nairobi operating theatres. 32elderly (ASA physical status I–III) patients scheduled for lower limb and pelvic surgeries were randomized to receive 2.5 mls of 0.5% hyperbaric bupivacaine intrathecally at the L3, 4 interspace(control group) or at the L5, S1 interspace (intervention group).
On arrival in the operating theatre, standard monitoring was applied with automated noninvasive blood pressure measurement, electrocardiography and pulse oximetry. Baseline

mean arterial blood pressure (MAP) and heart rate (HR) were recorded while lying down comfortably and the average of 3 readings was taken as the baseline blood pressure. Subsequently, the blood pressure was measured at 2.5 min intervals in the position of surgery. All patients received 500ml of lactated Ringer's solution during induction of the allocated spinal anesthetic technique to run over the first 30 minutes.The patient was then positioned in a sitting position. After cleaning and draping, the allocated interspace was identified by palpation then confirmed with the assistance of an X ray image intensifier. Local anesthesia was then infiltrated. The spinal anesthesia was performed with the patient in the sitting position using a midline approach at the L3, 4 interspace for the standard group; and the L5, S1 interspace for the low block group. A 22 or 25 gauge spinal needle was used and after CSF flow was obtained, 2.5 mls of hyperbaric bupivacaine was injected over 10 seconds withbarbotage. The patient was then turned supine and left supine for 10 minutes. Five minutes from completion of the intrathecal injection (taken as the point of removal of the spinal needle), the sensory block level to both light touch and cold were checked at 2.5 min intervals until there was no change in 3 consecutive readings. To assess the level of block to light touch, a dry cotton wool swab was used; and for loss of cold sensation, cold ethychloride spray was used.(55,56)

Surgery was allowed to commence as soon as the sensory block height to light touch had been tested pre-incision and reached the tenth thoracic dermatome (T10).
If pain or discomfort was felt at any point duringthe operation,the patient was offered the option of GA or supplementary analgesia with IV adjuncts - fentanyl 1-2 mcg/kg and IV paracetamol 1gm.

Hypotension (defined as a reduction in MAP of more than 20% from baseline determined just before the administration of spinal anesthesia or MAP below 60mmHg) was treated with ringer's lactate 200mls bolus, ephedrine boluses of 6 mg to a total of 30 mg and consequently fluids titrated to effect on the blood pressures. If this was not enough to return the blood pressures to a MAP above 60mmHg, phenylephrine boluses 50mcg titrated to effect were used.

Bradycardia (defined as a heart rate below 60 beats per minute) was treated with atropine 0.3mg to 0.6mg titrated to effect.

The presence of intraoperative nausea, vomiting, pruritus, and shivering was noted and treated appropriately. Rescue antiemetic drugs using a combination of IV ondansetron 4mg and dexamethasone 8mg were administered. Discomfort from post anaesthetic shivering was treated with IV pethidine 25mg.(49; 50; 51)

Post operative analgesia was prescribed at the discretion of the primary anaesthesiologist attending to the patient.

7.7 DATA MANAGEMENT

7.7.1 Data collection procedure and tools

The patient's bio data, medical history and level of spinal injection used relevant to the study were recorded by the anaesthesiologist who performed the SA (appendix 3 part A)
Intraoperative data was collected by the principal investigator or a trained research assistant after SA had been performed using a data collection form (appendix 3 part B).

7.7.2 Data storage

All the raw data in this study was filed in a suitable box file which is stored in a lockable filing drawer. All data was verified for completion by the principal investigator before filing. Every precaution was taken to respect the privacy of patients whose data was collected and analyzed in this study. Patient data was only identified by a unique identifier number. In the course of monitoring data quality and adherence to the study protocol only the study supervisors and the principal investigator could refer to the recruited patients' medical records.

7.7.3 Data analysis

Data analysis was undertaken using the STATA/SE 11 (from StrataCorp USA) with the input of a statistician who has been involved since the beginning of the study.

Descriptive statistics were used to compare patients' characteristics in terms of age, sex, height, weight, baseline blood pressures and heart rates. Student's T test was used to compare if the 2 sample sizes were statistically different.

The Chi test was used to compare the proportions of hypotension between the two groups.

The Student's T test was used to compare the differences between blood pressure reduction and heart rates reduction between the two groups.

Survival time analysis (Kaplan Meir) was used to analyze the time to hypotension. Log rank test was used to compare the rate of hypotension in the 2 groups

The differences between the two groups in total fluids given and total ephedrine and phenylephrine used werecompared using Mann-Whitney non parametric statistical test.

Maximum sensory block achieved was analyzed using the Mann-Whitney test.

The percentage of patients converted to general anaesthesia in both groups was analyzed using the Z test for equality of proportions.

The statistician offered guidance during data entry, analysis and presentation of the final statistics.

7.8 Ethical consideration

The study was performed following approval from the Ethical and Scientific Research Committee at the Aga Khan University, East Africa.

Patients were recruited after having signed an informed consent, which clearly stated that it was a study being conducted and that their information would be kept confidential and may be published(appendix 1 and 2).The patients were made to understand that they would receive health care as all other patients who came to theatre, and that they would not be denied care if they declined to participate in the study.

An explanation on the study procedure was given to the patient both verbally and using a written form (appendix 1). It was also made clear that there would be no direct benefit to the patient arising from participation in the study, but that the results could be used to change local practice in the future. There were no added expenses to the participants.
After the explanation on the study, the patientsvoluntarily signed the consent form and were recruited into the study.

An imaging intensifier, which emits very low radiation dose, was used(58,59).Imaging was kept at a minimum and patients did not undergo any more radiation exposure than would be normally required for the confirmation of the interverterbral space.
All the staff involved wore protective shielding with lead aprons and thyroid shields to prevent exposure to scatter radiation during use of the imaging intensifier(58,59).

The operation did not start until it was confirmed by testing pre-incision that the anesthesia was adequate for the procedure.

In case of any discomfort or pain, we used I.V paracetamol and I.V fentanyl 1-2 mcg/kg and the patient was offered general anesthesia (GA).

Postoperative analgesia was prescribed at the discretion of the attending anaesthesiologist.

8.0 RESULTS

Thirty two elderly (aged above 60 years) patients who underwent spinal anaesthesia were included in this study. Their baseline characteristics are shown in Table 1.

TABLE 1: Patients' baseline characteristics

	Control	**Intervention**	
	Mean(SD)	Mean(SD)	P Value
Age (years)	65.75(4.64)	68.75(8.72)	0.883
Weight(kg)	77.625(10.81)	76.19(19.66)	0.400
Height (cm)	162.94(6.84)	166.25(12.47)	0.820
BMI	29.22 (3.581)	27.27 (5.09)	0.110
Sex %Female (Male)	43.75 (56.25)	31.25 (68.75)	0.465
Chronic Illness(%)	81.25	87.5	0.626
Anti-hypertensives use	50%	50%	1
Other drugs	68.75%	50%	0.28

(Data are mean $\pm$ SD, T-test used to analyse normal distributed variables and Mann-Whitney U test for skewed data)

The 2 groups were similar with no significant difference in their baseline characteristics. The mean age was 66 years in the control group and 69 years in the intervention arm. The weight was 77.6 kgs and 76.2Kgs for the control arm. The body mass index (BMI)in the control arm was 29.22 versus 27.27 in the intervention arm but this difference was not statistically significant. There were more men in both groups of the study. 81.25% of the patients in the control group had chronic illnesses compared to 87% in the intervention group while in both groups 50% of the patients were on anti-hypertensive medication.

Table 2:Types of Procedures

Procedures	Operation	Frequency	Percentage	Cumulative percentage
Urological				
	TURP	10	31.25	31.25
	Bilateral orchidectomy	1	3.125	34.375
	Bladder neck incision	1	3.125	37.5
Orthopaedic				
	Total knee replacement	5	15.625	53.125
	ORIF femur	4	12.5	65.625
	ORIF tibia	2	6.25	71.875
	Knee arthroscopy	2	6.25	78.125
General surgical				
	Debridement	2	6.25	84.375
	Inguinal herniorrhaphy	1	3.125	87.5
	Hydrocoelectomy	1	3.125	90.625
Gynaecological				
	TAH	1	3.125	93.75
	TVH	1	3.125	96.875
	VVF repair	1	3.125	100
Total		32	100	

ORIF-Open reduction internal fixation;TAH –Total abdominal hysterectomy

TURP-trans-urethral resection of the prostate; VVF-Vesiculo-vaginal fistula

The results demonstrated on table 3 were set out to show the primary outcome as the proportion of hypotension in the two groups. Further, in table 4, the results show the number of episodes of hypotension recorded during the period of the study(45 minutes), followed by some descriptive statistics and graphs on the same. The results onthe secondary outcomes - change in heart rate, the use of vasopressors and the level and time of onset of maximum blocks between the control (L3,4) and the intervention (L5,S1) groups, have been shown on tables 6 and 7 . The data was analysed to verify statistical significance,which was defined as p value less than 0.05.

TABLE 3 Proportion of hypotension (primary outcome)

	Control (L3,4)	Intervention (L5,S1)
No hypotension n(%)	5 (31.25%)	4(25%)
Hypotension n(%)	11(68.75%)	12(75%)
Total	16(100%)	16(100%)
	P value 0.694	

There was 68.75% incidence of at least one episode of hypotension in the control group (L3,4) and 75% in the intervention group. This was not found significant (p value of 0.694).

TABLE 4 Episodes of hypotension during the first 45 minutes of SA

	Control (L3,4)	Intervention (L5,S1)	Total
No hypotension n (%)	95 (59.38%)	119 (74.38%)	214(66.88%)
Hypotension episodes n (%)	65 (40.63%)	41 (25.62%)	106 (33.13%)
Total n (%)	160 (100%)	160 (100%)	320 (100%)
Pearson chi test 8.1256			
P value0.004			

There were 10 blood pressure readings for each patient during the first 45 minutes of the spinal anaesthesia (at 2.5min,5 min,7.5min,10min,12.5 min,15 min,20 min,25 min,30min and 45min),giving a total of 320 readings.106 out of these 320 readings were hypotensive pressures. The control group had 65/106 while the intervention group had 41/106 hypotensive episodes.There was a significant difference in the number of hypotensive episodes between the two groups (p value 0.004).

FIGURE 1 Number of episodes of hypotension per patient during the first 45 minutes of spinal anaesthesia

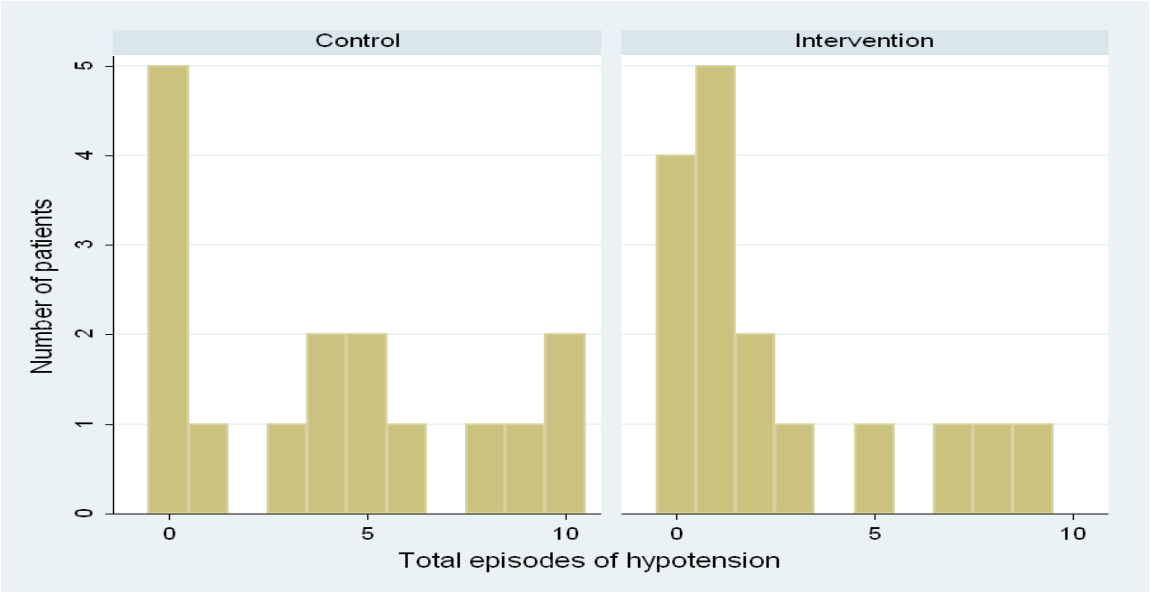


FIGURE 2 Mean Arterial Pressures (MAP) over time

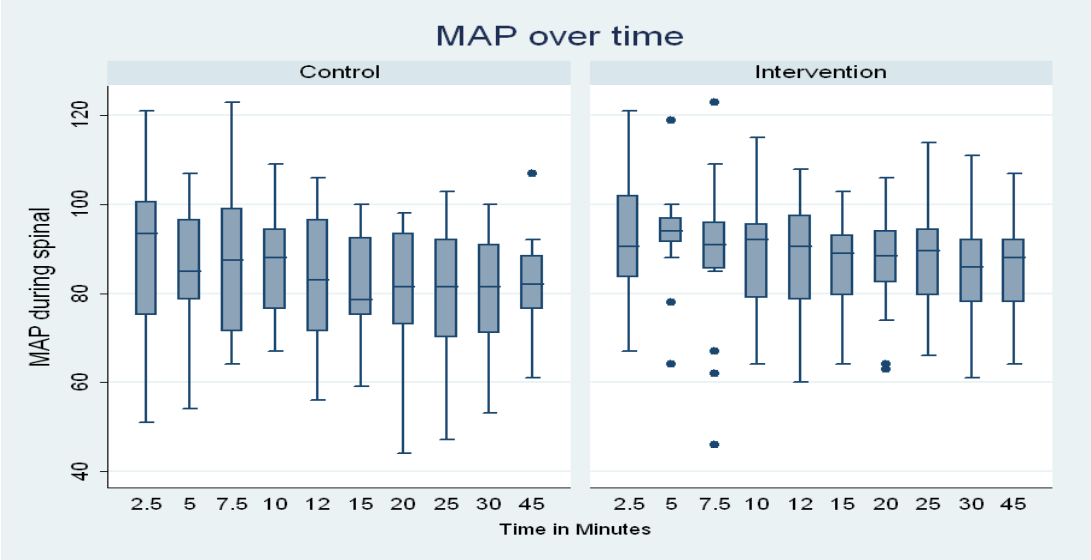


FIGURE 3 Change in Mean arterial pressure(MAP) over time

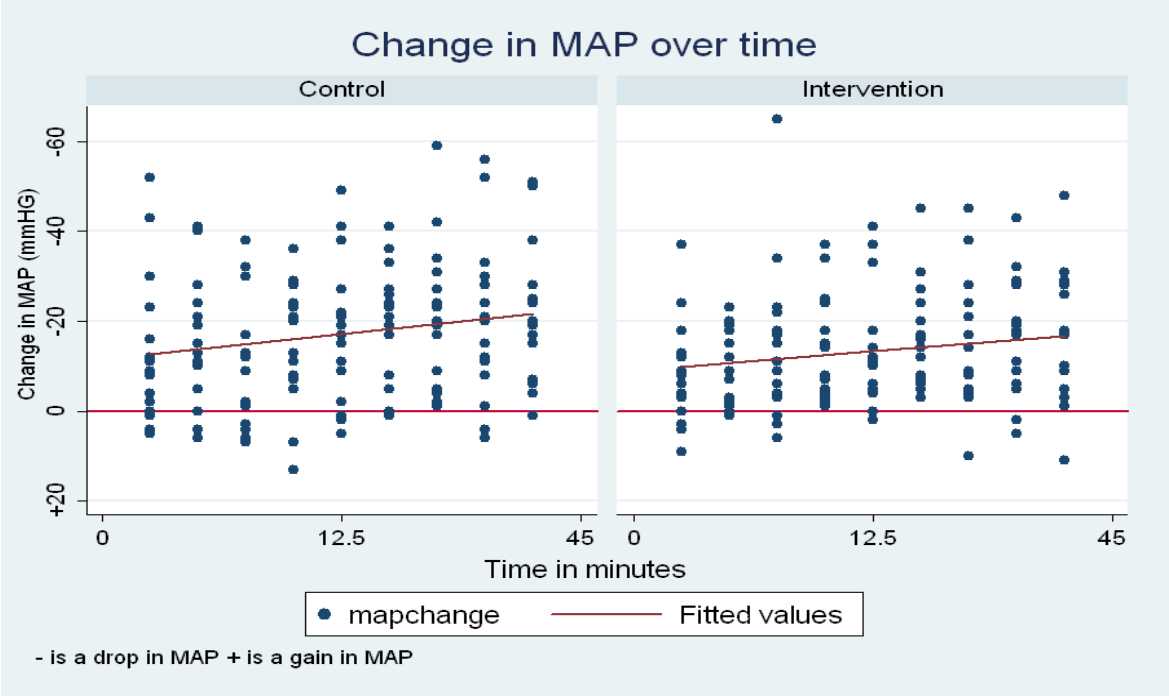
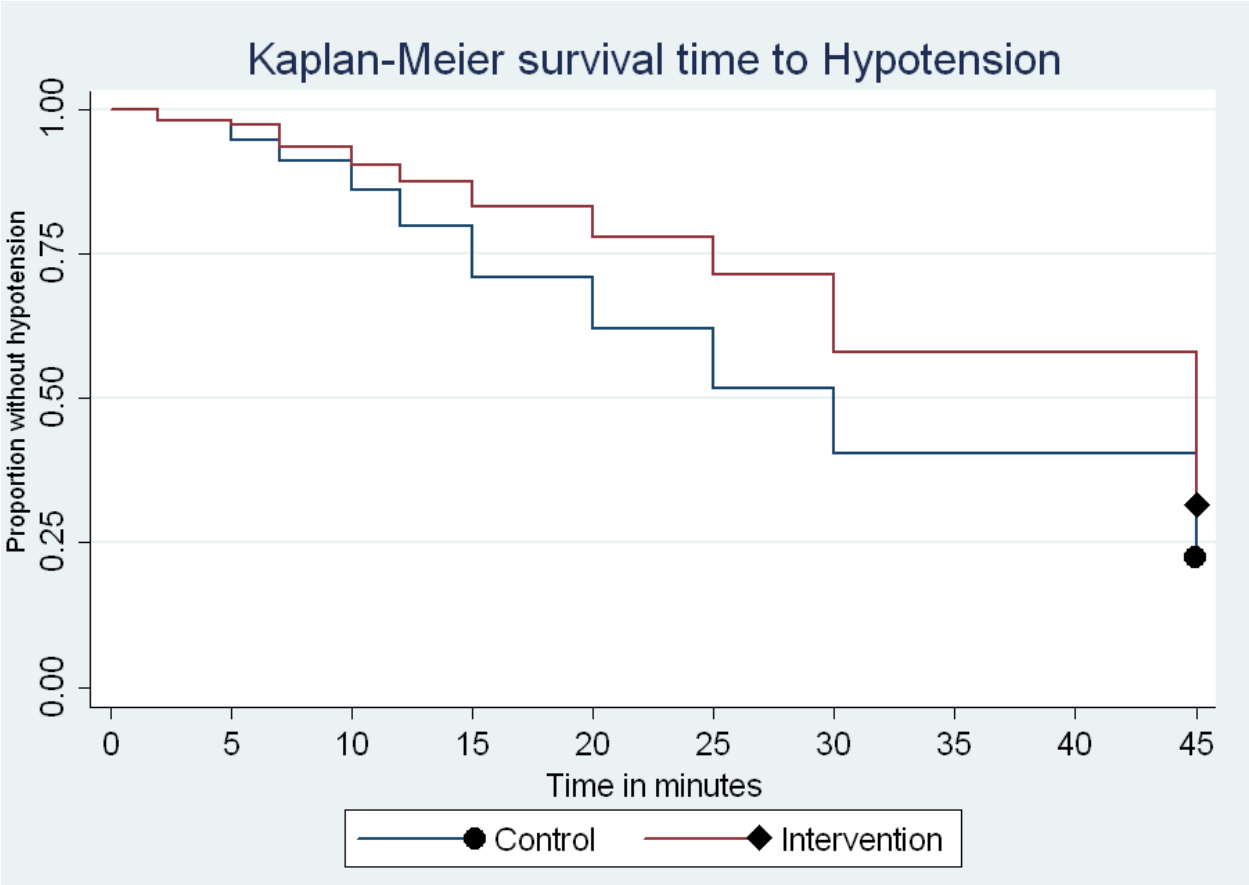


TABLE 5 Linear regression analysis comparing control versus intervention for Mean Arterial Pressure (MAP) change

	Co-efficient	Standard error	t	P value
MAP change	-0.0046	0.0019	-2.38	0.018

A linear regression analysis revealed a statistically significant difference between change in mean arterial pressures (MAP) in the control group (L3,4) and the intervention group (L5,S1).

FIGURE 4 Kaplan –Meir survival time to hypotension



The above Kaplan Meir curves demonstrate that time to onset of hypotension was most likely to occur between ten and thirty minutes in both groups; with the control group having more episodes of hypotension compared to the intervention. The proportion of hypotension after 30 minutes becomes similar in the 2 groups.

Table 6 Secondary outcomes

	Control(SD)	Intervention(SD)	P value
Bradycardia	10%	15%	0.132
Fluids used mls (SD)	1006(374)	606 (211)	0.001
Ephedrine used, in mg(SD)	15 (10.8)	8.4 (7.1)	0.288
Ephedrine used (% patients)	37.5%	31.25%	0.710
Converted to GA n (%)	1(6.25%)	2(12.5%)	0.544
Supplementary analgesia (I.V Fentanyl) n (%)	2(12.5%)	1(6.25%)	0.544
Time ,in minutes ,to maximum block(SD)	9.06(5.2)	13.07(7.9)	0.0001

GA-General anaesthesia, I.V –intravenous, SD –Standard deviation

There was a significant difference in the amount of intravenous fluids (Ringer's Lactate) used between the two groups (p= 0.001); but not in the amount of vasopressors used in the patients. There was no difference in the number of patients converted to general anaesthesia or those who required supplementary intravenous fentanyl. The difference in the time to maximum sensory block achieved was found to be significant (p=0.0001),being longer in the intervention arm.

FIGURE 5 Heart rate changes over time

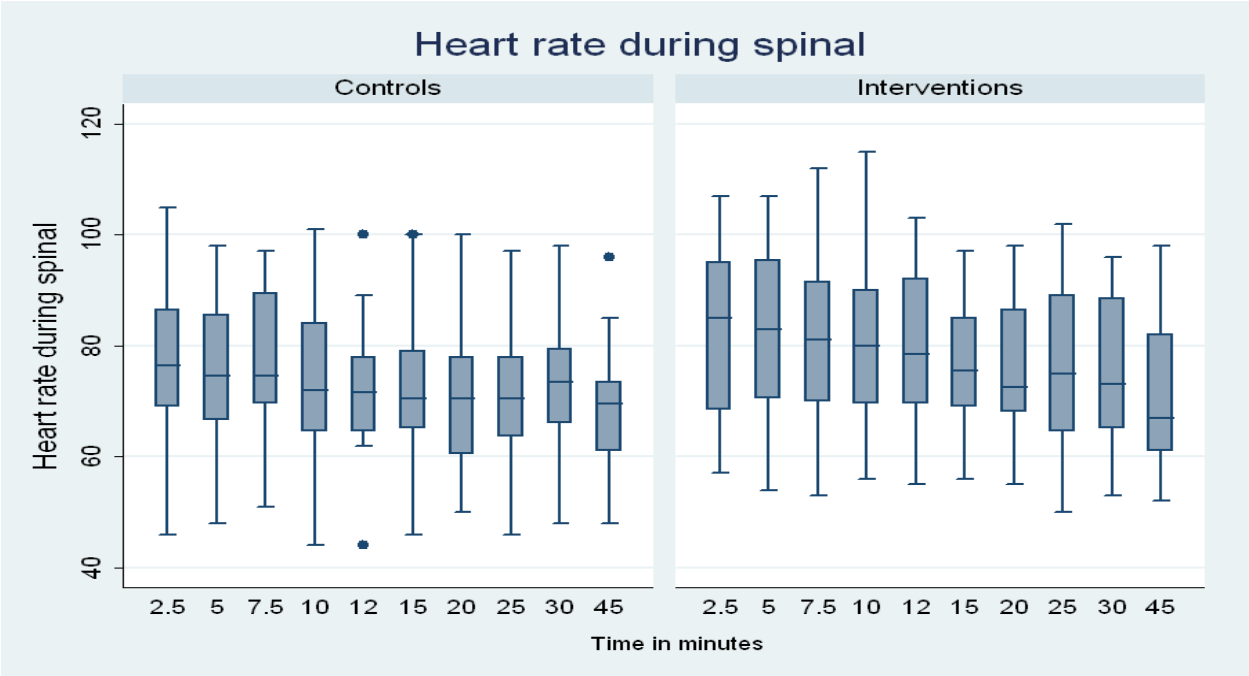


TABLE 7Level of maximum sensory block

Sensory block	Intervention	Control	
	Mean(SD)	Mean(SD)	P Value
Block to light touch	T9.9(2.0)	T8.8(2.0)	0.08
Block to cold	T10.1(1.6)	T9.1 (2.1)	0.054

FIGURE 6 Level of sensory block to cold

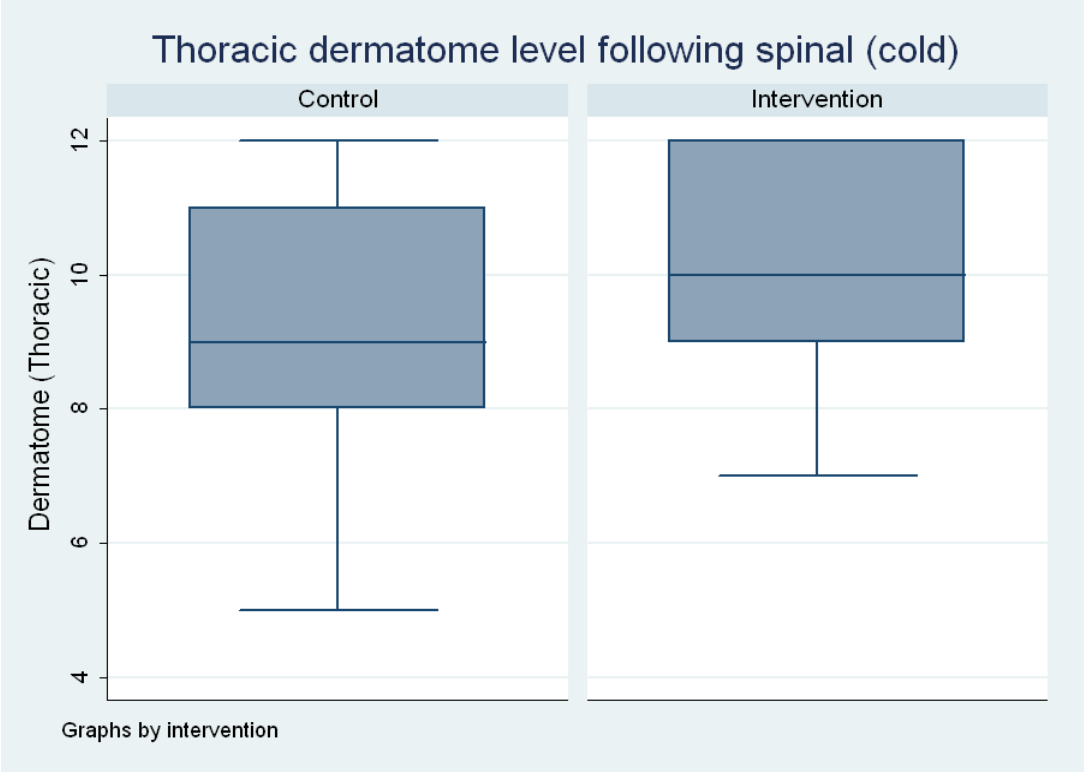
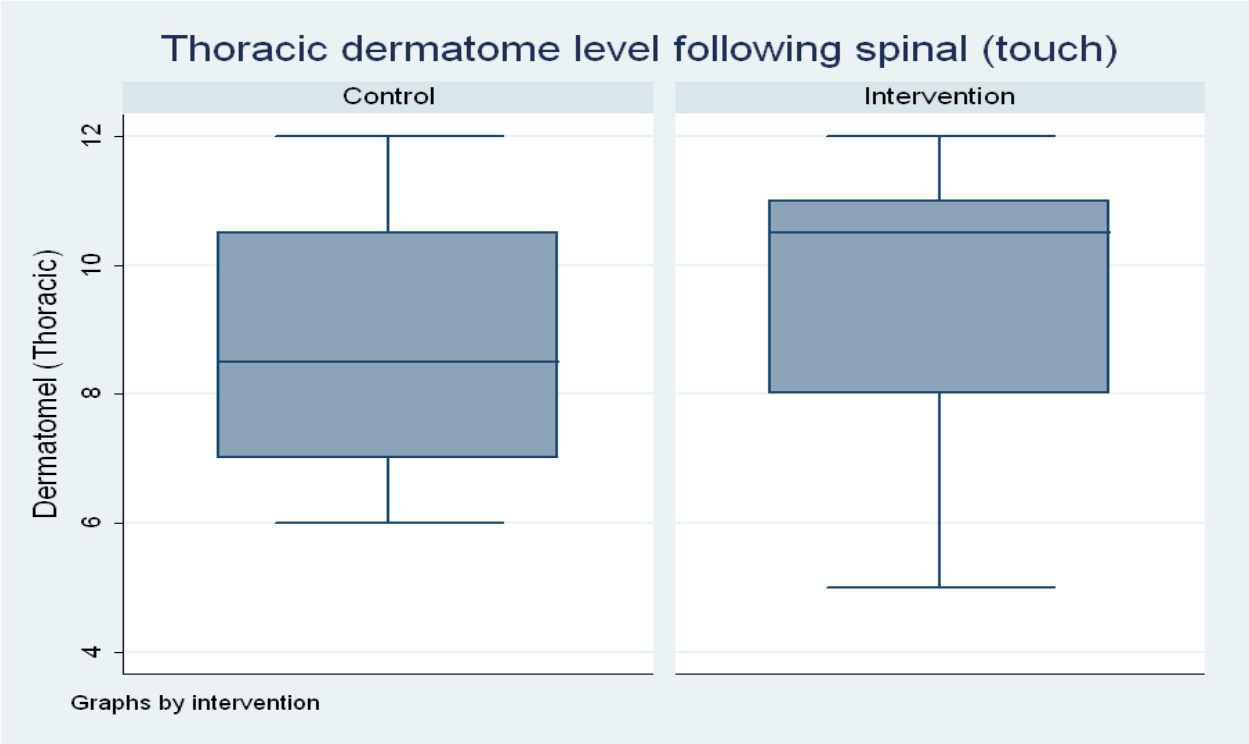


FIGURE 7 Maximum sensory block to touch



There was no statistically significant difference in the peak block heights to both cold and light touch between the two groups (table 4).

9.0 DISCUSSION

In this randomized controlled study, 32 patients above the age of 60 years were enrolled to undergo spinal anaesthesia either at the level of L3,4 (control group) or at the level of L5,S1 (intervention group) for various procedures. There were no significant differences in their demographic characteristics (Table 1).The data was collected and recorded in the first 45 minutes of the spinal anaesthesia.

The principal finding of this study was that the total numbers of episodes of hypotension were significantly less in the intervention group (L5, S1) compared to the control group (L3,4). In the first 45 minutes of spinal anaesthesia, there were 65 episodes of hypotension in the control group out of the total 106 episodes, and 41 in the intervention group (table 4). This difference was statistically significant (p value 0.004). However,the proportion of hypotension in the control group (L3,4) was 68.75% while that of the intervention group(L5,S1) was 75% (table 3). The difference in proportions was not statistically significant with a p value of 0.694. In this study, we definedhypotension as a 20% decrease in mean arterial pressures (MAP) from baseline or MAP of below 60mmHg. Based on case series of spinal anaesthesia performed at L5,S1,we had postulated that only 10% of the patients in the intervention group would have hypotension within the first 45 minutes of spinal anaesthesia[2]. The discrepancy between the postulated proportion in the intervention group(10%) and the results of the study(75%) was most probably due to methodological flaws in the anecdotal case series. In the anecdotal case series, no protocol was involved in the administration of fluids and vasopressors and the analysis was not rigorous enough. Furthermore, there is a paucity of published well designed studies on spinal anaesthesia at the level of L5, S1. The published case reports, of one patient each, showed haemodynamic stability in the participants(37,38). In contrast to our hypothesis, the proportion of hypotension was higher in the intervention group (75%) than in the control group (68.75%). The findings in the control group correspond to the published incidence of hypotension of 65% to 69%(19,20).The difference in the proportions of patients who had hypotension in the control and in the intervention groups was not statistically significant (p

[2] Anecdotal case series
Strategies to reduce the cardiovascular side effects of spinal anaesthesia by minimising the peak block height through performing the procedure at L5, S1 by Dr Thikra Sharif, Aga Khan University Hospital, Nairobi. The main observation was that the patients who received SA at L5,S1 had more stable haemodynamic variables compared to the conventional level of L3,4.

value 0.694). This shows that performing spinal anaesthesia at L5,S1 does not reduce the proportion of hypotension, thus disproving our hypothesis. These findings clearly show that although the proportion of patients who had hypotension was not reduced by performing spinal anaesthesia at the lower level of L5,S1 as hypothesized,the number of episodes of hypotension were significantly reduced making them more haemodynamically stable than thosepatients who had spinal anaesthesia performed at L3,4.

In the current study, bradycardia was defined as a heart rate below 60 beats per minute. The prevalence of bradycardia was 10% in the control group (L3, 4) and 15% in the intervention group (L5, S1), this difference was found to be statistically insignificant. These findings are similar to those of Carpenter et al who reported a 13% incidence of bradycardia (10). None of the patients required rescue atropine for the bradycardia as it either resolved spontaneously or responded to rescue ephedrine doses as the bradycardia was associated with hypotension. In this study, we did not record any other dysrhythmias on ECG, and none of our patients required cardiopulmonary resuscitation.

There was a statistically significant difference between the two groups in the amount ofintravenous fluids (Ringer's Lactate) used but no difference in the amounts of ephedrine used (table 6). This probably reflects the difference in the number of episodes of hypotension between the two groups as there were more episodes in the control group (L3,4) compared to the intervention(L5,S1) group. As per the study protocol, whenever hypotension was noted, a bolus of intravenous fluid was administered before administering a vasopressor. This also reflects the practice in the study hospital, where the anaesthesiologist administers a crystalloid bollus in case of a decrease in blood pressures, and if there's no response, vasopressors (ephedrine)boluses are added. None of the patients received phenylephrine.

During this studyone patient(6.25%) in the control group was converted to general anaesthesia in the control group and two patients (12.5%) in the intervention group(p value 0.544). The reason was that in all the 3 patients, there was an inadequate sensory block for the procedures.

The differences in the peak sensory block both to cold and touch,between the two groups, were not found to be statistically significant(table 4).These findings correspond to those of Veering et

al who did not find any difference in maximum level of analgesia when comparing spinal anaesthesia at L3,4 and L4,5 in elderly patients(39). During the study, the mean time to maximum block was 9 minutes and 13 minutes for the control group and intervention group, respectively (table 3). This difference was statistically significant but it was not found to be clinically significant as the cases were dealt with were not being performed as emergency cases.Previous published studies on spinal anaesthesia in elderly patients report a mean time to maximum onset of block as 15 minutes with a range of 11 to 20 minutes(39,51). This difference in time to maximal block was probably because our study tested for loss of sensation 5 minutes from completion of spinal anaesthesia then every 2.5 minutes interval until there was no change in 3 consecutive readings; while these previous studies tested for loss of sensation until 30 minutes after spinal anaesthesia(39,51).

As it is well known that lumbar spaces may be misidentified by use of clinical palpation alone, in this study an X ray image intensifier was used to overcome this technical challenge of accurately identifying the interspaces in all the patients. Previous studies have found that clinical palpation of the lumbar interspaces were only 30 % accurate (40; 42; 43; 44)

Performing spinal anaesthesia at the level of L5,S1 was found to provide an adequate block for a wide range of urological procedures (TURP, bladder neck incision, orchidopexies), orthopaedic procedures on the lower limbs, gynaecologic (hysterectomies, vaginal fistula repair) and general surgical procedures like inguinal herniorrhaphies (Table 2).Peak sensory block, use of supplementary analgesia(intravenous fentanyl) and the rate of conversion to general anaesthesia were used as indicators for adequacy of block achieved for the surgical procedures performed. These differences were found to be statistically insignificant. The rate of conversion to general anaesthesia and the use of intravenous fentanyl in the intervention group werealso not significantly different from the control group (table 6).

Although performing spinal anaesthesia at the lower level of L5,S1 (compared to the conventional level of L3,4) does not eliminate the occurrence of hypotension, there are significantly less hypotensive episodes per patient with no difference in heart rate changes and a similar peak sensory block. In view of these findings, we concluded that in elderly patients,a

spinal anaesthetic at L5,S1 results in a more haemodynamically stable patient, with a sufficient sensory blockade achieved, thus making it a safer level for performing spinal anaesthesia.

9.1 Strengths of the study

After a rigorous literature review, it appears that this is the first prospective randomised controlled study on performing spinal anaesthesia at the level of L5,S1. Therefore, this study will add to the scarce body of literature and knowledge on spinal anaesthesia performed at the level of L5,S1 and probably form a basis for many other studies on spinal anaesthesia in the future.

In the current study, fluoroscopy was used to confirm the spinal interspace used for spinal anaesthesia. This gives 100% accuracy in the identification of the spinal interspaces used for the study.

9.2 Limitations of the study

The study was conducted at a single centre and involved a relatively small number of patients and a wide range of procedures.This may impact on the generalisability of the results of this study.

The calculation of the power of the current study was based on a small number of anecdotal case series, and not a large randomised clinical trial due to paucity of published studies on spinal anaesthesia at the level of L5,S1. Thecase series was retrospective, no protocol was involved in the administration of fluids and vasopressors and the analysis was not rigorous enough. This probably explainsdiscrepancy between the postulated proportion of hypotension and the findings of the study.

10.0 CONCLUSION

On the basis of the results of this study,there was no difference between the proportion of hypotension in elderly patients undergoing spinal anaesthesia at the level of L5,S1 and those undergoing spinal anaesthesia at the level of L3,4 . However, the number of hypotensive episodes were significantly more in the control group (L3, 4) than in the intervention group (L5,S1). This difference was statistically significant. The difference in heart rate change(bradycardia) between the two groups was also not statistically significant. Therefore, we conclude that there were less episodes of hypotension when spinal anaesthesia is performed at the level of L5,S1 compared to L3,4 in the elderly patient.

In addition, performing spinal anaesthesia at the level of L5, S1 in the elderly patients was found to provide an adequate block for a wide range of urological procedures (TURP, Bladder neck incision, orchidopexies), orthopaedic procedures on the lower limbs, gynaecologic (hysterectomies, vaginal fistula repair) and general surgical procedures like inguinal herniorrhaphies.

11.0 RECOMMENDATIONS

A large, controlled and perhaps, multicenter study involving one type of procedure, ashomogeneityis required to validate these findings.

12.0 DISSEMINATIONOF THE FINDINGS

The findings of this study have the potential of changing the practice in performing spinal anaesthesia; and could be extrapolated for other groups of patients undergoing spinal anaesthesia. Therefore, the results will be shared with all clinicians (anaesthesiologists) at the Aga KhanUniversity hospital, Nairobi. In addition, the findings of this study will be submitted to a peer reviewed medical journal for possible publication.

13.0 BIBLIOGRAPHY

1. Me K. of the practice of regional anaesthesia. Journal of the Royal Society of Medicine. 1990;83(November):709–12.

2. Sabaté S, Anesthesiologist S. Anesthesia for urological surgery in a European region with. Journal of Clinical Anesthesia [Internet]. 2009;21(1):30–7. Available from: http://dx.doi.org/10.1016/j.jclinane.2008.06.017

3. Rodgers A, Walker N, Schug S, Mckee A, Kehlet H, Zundert AV, et al.Reduction in postoperative mortality and ,morbidity with epidural and spinal anaesthesia: results from an overview of randomised trials.BMJ 2000;321:1-12.

4. Klopfenstein CE, Herrmann FR, Clergue F, Forster A, Michel JP. The Influence of an Aging Surgical Population Anesthesia Workload : A Ten-Year Survey. Anesthesia-Analgesia 1998;86: 1165-70

5. Cook DJ, Rooke GA. Priorities in Perioperative Geriatrics. Anesthesia & Analgesia [Internet]. 2003 Jun [cited 2011 Feb 22];:1823–36. Available from: http://content.wkhealth.com/linkback/openurl?sid=WKPTLP:landingpage&an=00000539-200306000-00051

6. Covert CR, Fox GS. Anaesthesia for hip surgery in the elderly. Canadian journal of anaesthesia = Journal canadiend'anesthésie [Internet]. 1989 May;36(3 Pt 1):311–9. Available from: http://www.ncbi.nlm.nih.gov/pubmed/2655951

7. Salonia A, Crescenti A, Suardi N, Memmo A, Naspro R, Bocciardi AM, et al. General versus spinal anesthesia in patients undergoing radical retropubic prostatectomy: results of a prospective, randomized study. Urology [Internet]. 2004 Jul [cited 2011 Feb 24];64(1):95–100. Available from: http://www.ncbi.nlm.nih.gov/pubmed/15245943

8. Dobson PMS, Caldicott LD, Gerrish SP, Cole JR, Channer KS. Changes in haemodynamic variables during transurethral resection of the prostate : comparison of general and spinal anaesthesia. BJA 1994;267–71.

9. Chung F , Meier R,Lautenschlager,Carmichael.General_or_Spinal_Anesthesia__Which_is_Better_in.26[1].pdf. Anesthesiology 67:422-27

10. Carpenter RL, Caplan R a., Brown DL, Stephenson C, Wu R. Incidence and Risk Factors for Side Effects of Spinal Anesthesia [Internet]. Anesthesiology. 1992 Jun;76(6):906–16. Available from: http://content.wkhealth.com/linkback/openurl?sid=WKPTLP:landingpage&an=00000542-199206000-00006

11. Daniel, C. Spinal (Subarachnoid) Block: A review of 11,574 cases. Clinical Anesthesia.JAMA,1966;195: 907-12 .

12. Kopp SL, Horlocker TT, Warner ME, Hebl JR, Vachon C a, Schroeder DR, et al. Cardiac arrest during neuraxial anesthesia: frequency and predisposing factors associated with survival. Anesthesia and analgesia [Internet]. 2005 Mar [cited 2010 Jul 31];100(3):855–65, table of contents. Available from: http://www.ncbi.nlm.nih.gov/pubmed/15728079

13. Pollard JB. Cardiac Arrest During Spinal Anesthesia: Common Mechanisms and Strategies for Prevention. Anesthesia & Analgesia. 2001;4(16):252–6.

14. Cousins MJ, Bridenbaugh PO. Neural blockade in clinical anesthesia and management of pain, Issue 494 [Internet]. Lippincott Williams & Wilkins; 1998 [cited 2011 Mar 3]. Available from: http://books.google.com/books?id=jvema9PNEPgC&pgis=1

15. Greene NM. Review Article Uptake and Elimination of Local Anesthetics during Spinal Anesthesia. Anesthesia & Analgesia. 1983;62:1013–24.

16. Greene NM. Review Article Distribution of Local Anesthetic Solutions within the Subarachnoid Space. Anesthesia-Analgesia. 1985;64:715-30.

17. Critchley LAH. Hypotension, subarachnoid block and the elderly patient.Anaesthesia. 1996;51:1139-43.

18. Mccrae AF, Wildsmith JAW. PREVENTION AND TREATMENT OF HYPOTENSION DURING CENTRAL NEURAL BLOCK.Changes. 1993;:672–80.

19. Critchley LAH, Stuart JC, Short TG. Haemodynamic effects of subarachnoid block in elderly patients. British Journal of Anaesthesia. 1994;73:464–70.

20. Meyhoff CS. Is it possible to predict hypotension during onset of spinal anesthesia in elderly patients ? B. Journal of Clinical Anesthesia [Internet]. 2009;21(1):23–9. Available from: http://dx.doi.org/10.1016/j.jclinane.2008.06.015

21. Hartmann B, Junger A, Klasen J, Benson M, Jost A, Banzhaf A, et al. The Incidence and Risk Factors for Hypotension After Spinal Anesthesia Induction: An Analysis with Automated Data Collection. Anesthesia & Analgesia. 2002;94:1521-9.

22. Stoelting RK, Miller RD. Basics of anesthesia [Internet]. Elsevier Health Sciences; 2007 [cited 2011 Mar 3]. Available from: http://books.google.com/books?id=NDrPkebF0FkC&pgis=1

23. Urwin SC, Parker MJ, Griffiths R. General versus regional anaesthesia for hip fracture surgery: a meta-analysis of randomized trials. British journal of anaesthesia [Internet]. 2000 Apr;84(4):450–5. Available from: http://www.ncbi.nlm.nih.gov/pubmed/10823094

24. Mauermann WJ, Shilling AM, Zuo Z. A comparison of neuraxial block versus general anesthesia for elective total hip replacement: a meta-analysis. Anesthesia and analgesia [Internet]. 2006 Oct;103(4):1018–25. Available from: http://www.ncbi.nlm.nih.gov/pubmed/17000823

25. Buggy D, Higgins P, Moran C, O'Brien D, O'Donovan F, McCarroll M. Prevention of spinal anesthesia-induced hypotension in the elderly: comparison between preanesthetic administration of crystalloids, colloids, and no prehydration. Anesthesia and analgesia [Internet]. 1997 Jan;84(1):106–10. Available from: http://www.ncbi.nlm.nih.gov/pubmed/8989009

26. Hartmann B, Junger A, Klasen J, Benson M, Jost A, Banzhaf A, et al. The Incidence and Risk Factors for Hypotension After Spinal Anesthesia Induction: An Analysis with Automated Data Collection. Anesthesia &Analgesia. 2002;94:1521-9.

27. Pitkanen M, Haapaniemi L, Tuominen M, Rosenberg PH. Influence of age on spinal anaesthesia with isobaric 0.5% bupivacaine.BJA. 1984;56: 279-84

28. Am C, Andrew M, Rs E, Middleton P, Sw S, Cyna AM, et al. Techniques for preventing hypotension during spinal anaesthesia for caesarean section (Review) Techniques for preventing hypotension during spinal anaesthesia for caesarean section.Cochrane Library. 2010;(11).

29. Baraka a S, Taha SK, Ghabach MB, Sibaii a a, Nader a M. Intravascular administration of polymerized gelatin versus isotonic saline for prevention of spinal-induced hypotension. Anesthesia and analgesia [Internet]. 1994 Feb;78(2):301–5. Available from: http://www.ncbi.nlm.nih.gov/pubmed/8311283

30. Jarvela K, SeppoE.The Comparison of Hypertonic Saline (7.5%) and Normal Saline (0.9%) for Initial Fluid Administration Before Spinal Anesthesia. Anesthesia-Analgesia. 2000;91:1461-5.

31. Arndt J, Krauth J. Joachim 0. Arndt, Bernd Marquardt. Incidence and time course of cardiovascular side effects during spinal anesthesia after prophylactic administration of intravenous fluids or vasoconstrictors.Anesthesia- Analgesia. 1998;87:347-54

32. Coe a J, Revanäs B. Is crystalloid preloading useful in spinal anaesthesia in the elderly? Anaesthesia [Internet]. 1990 Mar;45(3):241–3. Available from: http://www.ncbi.nlm.nih.gov/pubmed/2334037

33. Critchley L.A.H, Conway F. Hypotension during subarachnoid anaesthesia : haemodynamic effects of colloid and metaraminol. BJA.1996;76:734–6.

34. Nishikawa K, Yamakage M, Namiki A, Omote K. Prophylactic IM Small-Dose Phenylephrine Blunts Spinal Anesthesia-Induced Hypotensive Response During Surgical Repair of Hip Fracture in the Elderly.Anesthesia-Analgesia. 2002;95:751-6

35. Buggy DJB, Power CKP, Meeke RM, Allaghan SOC, Oran CM, Rien GTOB. Prevention of spinal anaesthesia-induced hypotension in the elderly : i .m .methoxamine or combined hetastarch and crystalloid. BJA. 1998;80:199–203.

36. Critchley L a, Stuart JC, Conway F, Short TG. Hypotension during subarachnoid anaesthesia: haemodynamic effects of ephedrine. British journal of anaesthesia [Internet]. 1995 Apr;74(4):373–8. Available from: http://www.ncbi.nlm.nih.gov/pubmed/7734252

37. Kardash K, King BW, Datta S. Spinal anaesthesia for caesarean section after Harrington instrumentation. Canadian journal of anaesthesia = Journal canadiend'anesthésie [Internet]. 1993 Jul;40(7):667–9. Available from: http://www.ncbi.nlm.nih.gov/pubmed/8403141

38. ISPUB - Taylor's Approach For Combined Spinal Epidural Anaesthesia In Post-Spine Surgery: A Case Report [Internet]. [cited 2011 Mar 3];Available from: http://www.ispub.com/ostia/index.php?xmlFilePath=journals/ija/vol10n2/taylor.xml

39. Eering BTHV, Iet PMTERR, Urm AGLB, Tienstra RS, Leef JWVANK. Spinal anaesthesia with 0 . 5 % hyperbaric bupivacaine in elderly patients : effect of site of injection on spread of analgesia. Anaesthesia. 1996;77:343–6.

40. Becker N, Callensen T, Christiansen C. Level of Injection in Spinal Anesthesia : Effect on Sensory Anesthetic Level.Regional Anesthesia 1993;18:44–6.

41. Olsen,Nielsen, Dorup J. Spinal analgesia with plain 0.5% bupivacaine administered at L2,3 or L4,5. BJA 1990;64:170–2.

42. Reynolds .Logic in the safe practice of spinal anaesthesia.Anaesthesia. 2000;55:1045–6.

43. Broadbent C.R, Maxwell W.B.Ability of anaesthesiologists to identify a marked lumbar interspace.Anaesthesia 2000;55:1122-6

44. Furness G, Reilly M.P, Kuchi S. An evaluation of ultrasound imaging for identification of lumbar interverterbral level. Anaesthesia 2002;57:277-80

45. Chakraverty RC, Pynsent PB, Westwood A, Chakraverty JK. Identification of the correct lumbar level using passive intersegmental motion testing.Anaesthesia, 2007;62:1121–5.

46. Render CA, Registrar S, Hospital SG. The reproducibility of the iliac crest as a marker of lumbar spine level.Anaesthesia 1996;51:1070–1.

47. Watson MJ, Evans S, Thorp JM. Could ultrasonography be used by an anaesthetist to identify a specified lumbar interspace before spinal anaesthesia .British Journal of Anaesthesia(BJA). 2003;90 (4):509–11.

48. Whitty R, Moore M. Identification of the Lumbar Interspinous Spaces : Palpation Versus Ultrasound. Anesthesia & Analgesia. 2008;106(2):538–40.

49. Axelsson KH, Edstrom HH, Widman GB. SPINAL ANAESTHESIA WITH GLUCOSE-FREE 0 . 5 % BUPIVACAINE : EFFECTS OF DIFFERENT VOLUMES. BJA. 1984;56:271

50. Beers R a, Kane PB, Nsouli I, Krauss D. Does a mid-lumbar block level provide adequate anaesthesia for transurethral prostatectomy? Canadian journal of anaesthesia = Journal canadiend'anesthésie [Internet]. 1994 Sep;41(9):807–12. Available from: http://www.ncbi.nlm.nih.gov/pubmed/7954998

51. Sundnes KO, Vaagenes P, Skretting P, Lind B. Spinal analgesia with hyperbaric bupivacaine: effects of volume of solution. BJA 1982;54:69-73

52. Kararmaz A, Kaya S, Turhanoglu S, Ozyilmaz MA. Low-dose bupivacaine-fentanyl spinal anaesthesia for transurethral prostatectomy.Anaesthesia 2003;58:526–30.

53. Fleiss, J. L. Levin, B, Park MC. Statistical Methods for Rates and Proportions 3rd Edition. Wiley; 2003.

54. Publication S press. STATA BASE REFERENCE MANUAL Release 11. STATA Corp LP;

55. Russell IF. ORIGINAL ARTICLE A comparison of cold, pinprick and touch for assessing the level of spinal block at caesarean section.Int J 0bstetric Anesth. 2004;13:146–52.

56. Bourne TM, Campbell F, Mushambi MC, May AE, Injirmary LR. Patients ' assessment of sensory levels during epidural analgesia in labour. Int J Obstetric Anesth. 1997;6:239–41.

57. Kranke P, Eberhart LH, Trame MR. Pharmacological Treatment of Postoperative Shivering : Anesthesia & Analgesia. 2002;(3):453–60.

58. Lo N.N, Goh, KhongK.S.Radiation dosage from use of image intensifier in orthopaedic surgery. Singapore Med J 1996;vol 37:69-71.

59. Goldstone KE, Wright IH, Cohen B. Radiation exposure to the hands of orthopaedic surgeons during procedures under fluoroscopic X-ray control. The British journal of radiology [Internet]. 1993 Oct;66(790):899–901. Available from: http://www.ncbi.nlm.nih.gov/pubmed/8220973

14.0 APPENDICES

14.1 APPENDIX 1 – PATIENT EXPLANATION FORM

A RANDOMISED CONTROLLED TRIAL COMPARING HAEMODYNAMIC STABILITY IN ELDERLY PATIENTS UNDERGOING SPINAL ANESTHESIA AT THE LEVEL OF L5,S1VS SPINAL ANAESTHESIA AT L3,4

EXPLANATION

Name of Principal Investigator: Dr. Karen Mbaya
Name of the Institution: Aga Khan University Hospital, Nairobi

Introduction

I am a medical doctor training for a postgraduate degree in Anaesthesiology at the Aga Khan University, Nairobi.

I am conducting a study to investigate the effect that performing a spinal anaesthetic at a lower level (L5, S1) than is normally performed (L3, 4) has on your blood pressures and heart rate during your operation. As you read through this form, there may be some words that you do not understand. Please do not hesitate to ask me to clarify or ask me to stop as we go through the information and I will take time to explain.

Purpose of the Research

Low blood pressure after spinal anaesthesia affects up to 69% of patients. The reason we are undertaking this study is to find out if performing this same spinal anaesthetic at a lower level will keep the blood pressures and heart rate as near normal as possible. Your care during this study will not be affected in any negative way if you agree to participate.

Type of Research Intervention

For this research you will receive standard treatment at AKUH, N, for your surgical procedure ,that is, spinal anaesthetic at the level of L3,4 or a low level spinal anaesthetic at L5,S1.We shall confirm the position that we are inserting the spinal anaesthetic by use of x ray imaging. The mode used for this kind of imaging emits low radiation and we shall only use it once.

Standard medication will be used for the spinal anesthesia. Before being recruited in this research you will be asked a series of questions to ensure that you will not suffer any adverse effects from having a spinal anaesthetic.

Participant selection

You are being asked to participate as part of a group of patients who will need spinal anaesthetic for their surgery.

Procedures:

If you agree to participate, we shall be performing a spinal anaesthetic in the routine standard procedure, and using the standard equipment. The only addition will be confirmation of the verterbral position we are at by use of x-ray. The costs of the image intensifier (x ray) use for the purpose of confirming location of the space, shall not be borne by you.

Risks and discomforts:

You are not expected to have any additional risks by participating in this study. Should you develop any pain or discomfort during the operation, we will use what is called a"rescue medicine." that has been proven to control pain. If you are still uncomfortable, you shall be offered general anesthesia (GA).

Benefits:

The knowledge obtained by this project will improve our understanding of the prevention of decrease in blood pressures after a spinal anaesthetic experienced by some patients. This may result in better ways to prevent or treat this complication in the future.

Compensation:

You will receive no compensation for participating in this study. In case commercial products such as new treatments are developed as a result of this study, you will not receive monetary or other benefits from the development of such products.

Confidentiality:

Any information you provide during the study will be kept strictly confidential. Your full name will not appear on any study document and only staff participating in the study will have access to the information you provide.

Right to Refuse or Withdraw:

Your participation in this research is entirely voluntary. You are free to choose whether or not you wish to participate. Your decision whether or not to participate will not affect your current or future relations with Aga Khan University Hospital.You will suffer neither penalties nor loss of any benefit should you decide not to participate. If for any reason, you are not eligible for the study, or decide not to participate, you will receive normal care and standard treatment and

medications. You are also free to withdraw from the study at any time should you wish to do so, for any reason.

Your co-operation is appreciated

Should you have any questions feel free to communicate with me concerning the study on the following address,

Dr Karen Mbaya

Tel number 0722-498 991

P.O. Box 30270-00100

Aga Khan University Hospital, Nairobi, Kenya.

14.2 APPENDIX 2

CONSENT FORM

I _____hereby consent to participate in this study, having been fully informed of the nature of the study by Dr. Mbaya.

Date _____ signed _____

I, Dr. Mbaya confirm that I have fully explained to my patient what this research involves and hereby undersign.

Date _____ Signed_____

14.3 APPENDIX 3 :DATA COLLECTION FORM

Part A-to be filled by the anaesthesiologist performing the SA

Patient's Study Serial No……..

Age ……..

Height (cm)……

Weight (kg) …….

Type of surgery…….

Any known chronic illnesses (please specify)……

…….

Pre –op medications used (within the last 3 days)

Drug	Yes (please specify)	No
Anti hypertensives		
Beta blockers		
Others		

Baseline vital signs BP Systolic ……Diastolic ……MAP…..

HR …….. Saturation (SPO2) ……..

SA interspace used (tick one)

- L3,L4
- L5,S1
- Other (specify)

Time completed SA (removed spinal needle from the back)……

Part B-To be filled by the research assistant after SA has been performed

Patient's Study Serial No……..

Time completed SA (removed spinal needle from the back)……

After completion of SA;

Time(mins)	2.5	5	7.5	10	12.5	15	20	25	30	45
SBP										
DBP										
MAP										
HR										

Lowest BP recorded; …… MAP…… (Time)…..

Highest BP recorded; ……. MAP ……. (Time)……..

Lowest heart rate recorded ……. (Time)……

Highest heart rate recorded …… (Time)……..

Use of ephedrine

- Yes , total dose used…….
- No

Need for additional phenylephrine

- Yes, total dose used …….
- No

Total amount of I.V fluids used (mls)

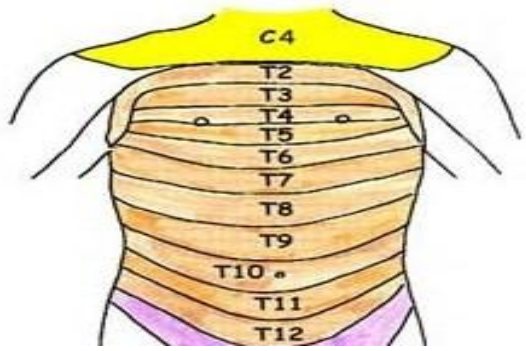
- crystalloids……..
- colloids……..

Time to maximum block (minutes from removing needle)…….

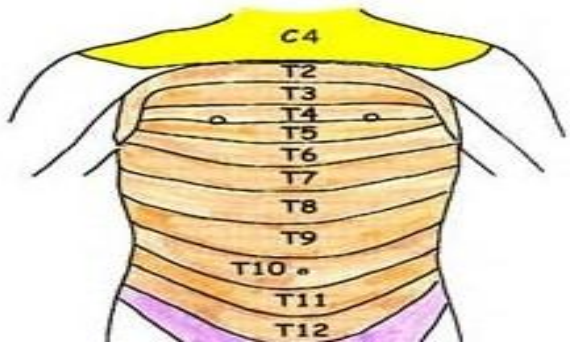
Is the patient able to (tick if yes; cross if no)

- Lift the leg
- Bend the knee
- Move the toes

Sensory block to light touch with dry swab (tick the most cephalad dermatome)



Sensory block to cold ethylchloride spray (tick the most cephalad dermatome)



Need for additional analgesics

- Paracetamol; dose used…….
- Fentanyl; dose used…….

Need to convert to GA ……

- Yes
- No

Reason for converting to GA…….

Position of patient during surgery (please indicate the time of change of position from supine)

- Lithotomy
- Supine
- Others ……(specify)

14.4 APPENDIX 4: BUDGET

ITEM	UNIT COST	UNITS	TOTAL (Kshs)
Research assistant	20,000	1	20,000
Statistician	30,000	1	30,000
Printing paper	350	2	700
Box files	250	2	500
Flash disks	1000	2	2000
X ray (image intensifier)	500	32	16,000
Totals			69,200