ADDIS ABABA UNIVERSITY

COLLEGE OF HEALTH SCIENCES

SCHOOL OF MEDICINE

DEPARTMENT OF ANESTHESIA

COMPARISON OF HEMODYNAMIC RESPONSE FOLLOWING SPINAL ANESTHESIA BETWEEN CONTROLLED HYPERTENSION AND NORMOTENSIVE PATIENTS UNDERGOING SURGERY BELOW THE UMBILICUS AT BLACK LION HOSPITAL: PROSPECTIVE COHORT STUDY, 2020

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Declaration

The undersigned people certify that the research entitled **Prospective cohort study on comparison of hemodynamic response following spinal anesthesia between controlled hypertension and normotensive patients undergoing surgery below the umbilicus at Black lion hospital from October 30, 2019-January 30, 2020;** A hospital based study is my original work and any literature and/or data cited in this article were listed in the reference section. Any assist done for this work has been given an acknowledgement.

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Abbreviations

ASA	American Society of Anesthesiology
BJR	Bezold Jarisch Reflex
BMI	Body Mass Index
BP	Blood Pressure
Bpm	Beat per Minute
CSF	Cerebrospinal Fluid
CO	Cardiac Out Put
DBP	Diastolic Blood Pressure
HR	Heart Rate
LAs	Local Anesthetics
MAP	Mean Arterial Pressure
MmHg	Millimeter Mercury
SA	Spinal Anesthesia
SVR	Systemic Vascular Resistance
SBP	Systolic Blood Pressure
BLH	Black line hospital
L3-L4	Lumbar Vertebrae 3 to 4
T5	Thoracic Vertebrae Five
CCB	Calcium channel blockers

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Abstract

Background: Hypotension and bradycardia is the most common complication associated with spinal anesthesia and more common in patients with history hypertension. Regular use of anti-hypertensive medication can prevent this complication. The occurrence of hypotension under spinal anesthesia among controlled hypertension and normotensive patients with age 40 years and above is still debated.

Objective: To compare hemodynamic response following spinal anesthesia between controlled hypertension and normotensive patients undergoing surgery below the umbilicus at Black lion hospital, Addis Ababa, Ethiopia, 2020.

Method: hospital- based Prospective cohort study design was conducted. A total of 110 elective patients with controlled hypertension (55) and normotensive (55) patients below the umbilical surgery under spinal anesthesia at black the lion hospital during the study period. The Sample was selected using a systematic sampling technique. Continuous data of independent and dependent variables were analyzed using an independent sample t test for normally distributed and Mann-Whitney U test for non-normally distributed between the study groups. Categorical variables between the study groups were analyzed using the chi-square test. Descriptive data were displayed using tables and figures. For continuous and categorical variables a P- value < 0.05 was considered to be statistically significant.

Results: A total of 110 patients were participated in this study**.** The incidence of hypotension in the controlled hypertension group (23.6%) was higher than the normotensive group (7.3%) with p-value 0.018. The occurrence of bradycardia was seen 12.7% in each groups with p-value > 0.05. There was a statistical significant difference in the mean systolic blood pressure, mean arterial pressure, mean heart rate and vasopressor consumption at the measurement time interval between controlled hypertension and normotensive groups.

Conclusion: Under spinal anesthesia patients with controlled hypertension are more likely to develop hypotension than normotensive patients but on the occurrence of bradycardia there was no statistical significant difference between the two groups. Vasopressor consumption is higher in controlled hypertension than the normotensive group.

Keywords: Spinal anesthesia, controlled hypertension, normotensive, hypotension, bradycardia

1: Introduction

1.1. Background

Hemodynamics is essential for a comprehensive and understanding the functioning of the circulatory system. The term hemodynamics is the basic measures of cardiovascular function, such as arterial blood pressure and cardiac output (1). Spinal anesthesia has tend to make lowering blood pressure and heart rate and it causes hemodynamic instability to patients undergoing surgery below the umbilicus. The adverse events are related to impaired perfusion of vital organ. Optimizing intraoperative hemodynamics after spinal anesthesia is one of the basic concerning of safe anesthesia (2).

Spinal anesthesia is one of the neuro-axial blocks with a massive and temporary interruption of nerve transmission with in the sub arachnoid space produced by injection of local anesthetic solution into the cerebrospinal fluids(3). Local anesthetics administered in the subarachnoid space block sensory, autonomic and motor impulses as the anterior and posterior nerve roots pass through the CSF. The site of action includes at the anterior and dorsal root of ganglion. Spinal anesthesia has been world widely used and continues to be Popular for surgeries involving the lower abdomen, perineum and lower limbs (4).

Spinal anesthesia is commonly used technique a total of 324,950 spinal anesthetics each year in the United Kingdom (31). When compared with general anesthesia, spinal anesthesia has many advantages including; few adverse effects on the respiratory system as long as excessively high blocks are avoided, a reduced risk of airway obstruction or aspiration, little risk of unrecognized hypoglycemia in an awake diabetic patient, less sedation, less nausea and vomiting, decreased blood loss, less immunosuppression, less cognitive impairment especially in the elderly, easy to perform for well trained, reliable and provides excellent operating conditions, less costly, normal gastrointestinal function returns faster, decreased incidence of deep vein thrombosis and pulmonary emboli formation (5).

Spinal anesthesia has common side effects like hypotension and bradycardia and a closed claims surveys was done in 2002 by the department of anesthesiology at Washington university in the USA, from 40,000 – 550,000 spinal anesthetics indicate, an incidence of cardiac arrest 0.04-10/10,000 (32) and also a large surveillance study was typically showed, the incidence of hypotension around 33% and bradycardia around 13%) in non-obstetrical population (3).

Spinal anesthesia is associated with many complications among controlled hypertension and normotensive patients. Peripheral vasodilation induced by sympathetic blockade after spinal anesthesia results decrease in venous returns and systemic vascular resistance. This could be one of the predominant mechanism for hypotension (6). The phenomenon may result from the blockade of cardio accelerator sympathetic fibers at the first to fourth thoracic (T1 to T4) nerve roots and possibly the "reverse" of the Bainbridge reflex (7).

Bain bridge (atrial reflex) stimulation of pressure receptors in the right atrial wall resulting from distension of large systemic veins. The reflex of Bain Bridge was described by Britain physiologists Arthur Bain Bridge, 1915 supposes there is a transient increase blood pressure in the right atrium by stimulating the atrial stretch receptors. Consequently both the heart rate and cardiac contractility are increased raising cardiac output. These receptors transmit information along the vagus nerve (10^{th}cranial nerve) to the central nervous system. This response results in the activation of sympathetic nerve path ways that serve to increase the strength of the heart muscle contraction and to increase heart rate (9).

Hypertension affects 26.4% of the global population (10). It is independent predictive factor of cardiac adverse events in non-cardiac surgery. Intraoperative hypotension is one of the most encountered factors associated with death related to spinal anesthesia. In the preoperative setting, the majority of anti-hypertensive medications should be continued until surgery. The long acting renin-angiotensin system antagonists, diuretics and calcium channel blockers may be stopped. Hypertension especially in the case of mild to moderate hypertension is not a cause for delaying surgery. However, hypotension is common after spinal anesthesia and episode of sever Hypotension can be detrimental to the patients especially with history of hypertension. Hypotension episodes should be promptly treated by intravenous phenylephrine and volume expansion. However, severe and rapidly progressing bradycardia demands aggressive treatment with epinephrine, atropine and followed by cardiopulmonary resuscitation if appropriate and according to their etiology (10).

1.2. Statement of the Problem

According to the world health organization shown that the total global surgical volume for the year 2012 was estimated to be 312.9 million operations. The operational procedure were performed in operating theaters that require spinal anesthesia (11). The hemodynamic instability after spinal anesthesia is common intra-operatively and the incidence of intraoperative hypotension ranges from 8 to 33% depending on the parameters used to define it (systolic blood pressure, usually < 80-90 mmHg) or on a 25% - 30% reduction of the initial systolic blood pressure (12).

Hypertension has been a major health problem in many parts of the world for more than a century. The Incidence of hypotension is more common in patients with history of hypertension. Anti-hypertensive medication decrease this effect by controlling blood pressure their varying effect on the cardiovascular system can alter the hemodynamic status of the patient at the initial phase of spinal anesthesia (4).

In Malaysia, according to the National Health and Morbidity Survey II, the prevalence of hypertension in the adult population has reached 24%. Hypertension is a risk factor for diseases such as coronary artery disease and cerebrovascular diseases. It has also become one of the most common causes for the postponing anesthesia and elective surgery (14). There are no universally accepted guidelines stating the arterial blood pressure values at which anesthesia should be fit and postponed. However, the Current accepted fit for anesthesia for controlled hypertension having BP < 140/90 mmHg as the result of treatment by pharmacologic therapy. In individuals with controlled hypertension having kidney disease and diabetic mellitus as the BP should be < 130/80 mmHg. In our practice, each year frequency of reaching above blood pressure level considered (15).

Decreasing of blood pressure most commonly seen in hypertensive patients associated with spinal anesthesia and more common in patients with a history of hypertension. Patients on regular use of antihypertensive medications can prevent this effect. In hypertensive patients, blood pressure fluctuations can be very closely related to blood volume changes after spinal anesthesia (16).

A prospective cohort study was done in 2002 Justus-Liebig-University Giessen at Germany shown that, hypotension due to spinal anesthesia was approximately twice as common in controlled hypertension than normotensive patients (4). Risk factors for early hypotension and

bradycardia after spinal anesthesia in non-obstetrical populations include a block height ≥T5, age ≥ 40years, female gender, weight, height, body mass index > 30 kg/m^2, ASA physical status II and above, history of hypertension, history of antihypertensive therapy, in case of ongoing beta blockers therapy, diabetes mellitus, anemia, lower baseline heart rate < 60 beat/minute, Baseline systolic blood pressure(SBP) < 100 mmHg, and spinal puncture above the level of L3 > L4 (3,6). High-level blockade (≥ T5) and the age ≥40 years) are the two main predicators of hemodynamic instability and hypotensive complication after spinal anesthesia, which has an incidence of 15.3 to 33% (7, 17 and 18).

The incidence of hypotension and bradycardia after spinal anesthesia in non-obstetric patients has been reported to be 33%-54% and 0.05-13%, respectively (19). Relative dominance of parasympathetic system, activation of Bezold -Jarisch reflex (BJR) and increased baroreceptor activity may lead to a triad of bradycardia, hypotension and some degree of peripheral vasodilation (20).

Perioperative hemodynamic instability is associated with spinal anesthesia. Simultaneously many multiple studies suggest that intraoperative cardiac complications associated with spinal anesthesia cause hemodynamic instability rather than acute intraoperative hypertension alone. A decrease of 40% in MAP and an episode of < 50 mmHg during surgery are associated with cardiac events in high-risk patients (21). Even short episodes of intraoperative MAP of < 55 mmHg are associated with acute kidney injury and myocardial injury after a non-cardiac surgery (22). At which the threshold used to define hypotension and duration an association with spinal anesthesia in between a perioperative stroke, acute kidney injury and cardiac events are not completely known (23). Intraoperative hypotension and bradycardia is one of the most encountered factors associated with death related to anesthesia (24). Major morbidity occurs in 3% to 16% of all surgical patients, with permanent disability and death occurring in 0.4% to 8.0% due to spinal hypotension (13).

On the other hand the current practice to treat hypotension is systolic BP of less than 85 or 90 mmHg or a decrease of greater than 25-30% from baseline. However the hemodynamic change underlie the decrease in SBP have not been investigated fully (25). The main factor causing hypotension in sympathetic block due to Spinal anesthesia is believed to occur due to two possible mechanisms. The first and widely accepted mechanism is arterial and venous vasodilation induced by sympathetic blockade after spinal anesthesia resulting in venous pooling

of blood and reduction in systemic vascular resistance (8) Based on this idea many scholars agreed that SA induced hypotension can be treated by crystalloid IV fluid, peripheral vasopressor and physical method there by increasing peripheral vascular resistance and venous returns (6).

The 2nd cause for spinal anesthesia induced hypotension is believed to be the blunted reflex tachycardia. This phenomenon is due to the result of cardio accelerator nerve block from T1 -T4 and the reverse of Bainbridge reflex (7). Currently various technique are being used to prevent hypotension and bradycardia which includes, co-loading IV fluid, vasopressor and physical methods such as: table down, patient head down (26).

The aged patients are prone to spinal anesthesia induced hypotension and bradycardia than young adults. This is because they may have coexisting degenerative cardiovascular diseases such as hypertension and physiological derangement. Additionally spinal anesthesia consequences a deranged reflex compensatory mechanisms resulted to hypotension and bradycardia (27).

Optimal perioperative blood pressure management appears to be a key factor of patient care after spinal anesthesia. Many factors influence the hemodynamic status of the patients such age, cardiac events, ant-hypertensive medication, type of surgery, type of anesthesia, and perioperative position (10). The current risk factors for hypotension in spinal anesthesia are also considered the presence of hypertension, a SBP > 150 mmHg, an advanced age > 40 years old, high body mass index, chronic alcohol consumption and emergency surgery (43).

Recently the incidence of cardiac arrest during spinal anesthesia is estimated at 2.73/10,000 patients. Patients are usually healthy, ASA I or II, male and with an increased basal vagal tone. In most cases a higher level T2 sensitive is detected with bilateral mydriasis after the cardiac arrest (44).

1.3. Significance of the study

Hypotension and bradycardia is common complication associated with spinal anesthesia. Sudden hypotension and bradycardia cause detrimental effect on the organ systems. However, still there is a controversy at which the threshold used to define hypotension and at which the percentage change of systolic blood pressure associated with spinal anesthesia will cause an acute kidney injury and cardiac events are not clearly investigated. Based on our study the percentage change of systolic blood pressure decreased by 25% and above from baseline between the groups may provide to define hypotension because most of the scholar agreed based on these criteria to define spinal anesthesia- related hypotension.

On the other hand in some study, different result of incidence hypotension found in different Literature and it shows no significant difference between the normotensive and controlled

Hypertension patients in incidence of hypotension caused by spinal anesthesia with hyper baric bupivacaine (3).

In another study, hypotension due to spinal anesthesia was approximately twice as common in Controlled hypertension patients (6, 16). Therefore based on this conflicting reports this Study will under taken to compare the hemodynamic status between controlled hypertension and Normotensive patients and which could be easily applicable at black lion hospital.

Another reason why I went to do this research, it is difficult to generalize research results from other countries because the management style, technique of monitoring and guideline used is differ from our country/ or study area due to economic and technology difference.

The finding it may generate information to black lion hospital the threshold used to define hypotension compute by percentage change of systolic blood pressure between controlled hypertension and normotensive group. The result also provide anesthesia management protocol in response to hypotension developed.

This study will be used as a base line or an input for the upcoming researchers

2. Literature review

Hypotension is the most frequent side effect of spinal anesthesia occurring in more than 30% of patients and CV complication. A decrease of BP can be considered a normal physiologic effect of spinal anesthesia. A study done in 2010 at Britain showed that, the incidence of hypotension during spinal anesthesia varies from 5% to more than 50% in non-obstetric patients. The Systolic BP less than 85–90 mm Hg or a decrease of 25%–30% from base line after spinal anesthesia given have been used to define hypotension (6, 29).

In study done by Ward RJ et al and Casati A et al, showed that a decrease in mean arterial blood pressure 21.3% from base line intraoperative following spinal anesthesia. The result also reported that a level of sensory block reached to T5 was resulted decrement in heart rate by 3.7%. The cardio accelerator fibers originate from T1-T4 and the level of spinal anesthesia affecting these dermatomes may cause bradycardia (30, 31).

Different incidences of hypotension have reported in different literature can be due to varying definitions and different methods of measurement. On similar pattern a study done in 2006 at Germany shown that an incidence rate of hypotension in non – obstetric population from 5% to 66% depending on the definition of hypotension limit (20).

A study done by Sanji N et al, 2012 in India a comparison about hypotension and bradycardia following spinal anesthesia between controlled hypertension and normotensive patients was showed at normal cardiac output maintained, a total peripheral resistance was decrease by 15-18% in normotensive healthy patients with total spinal a sympathectomy. While patients in controlled hypertension a systemic vascular resistance was decrease about 65% and cardiac output decreases only 10% with $p > 0.05$ (16).

A meta-analysis was done in 1989 about controlled Hypertension patients on management of BP following spinal anesthesia it showed, a moderate drop of SBP from base line by 18% to 24% in controlled hypertensive patients. Whereas patients with uncontrolled hypertension have a greater decrease in blood pressure and more frequent blood pressure fluctuations in response to sub arachnoid blockade with $p < 0.05$ (32).

In a prospective cohort study conducted in the School of Medicine, University of Zagreb, department of anesthesiology on hemodynamic changes among patients with hypertension and normotensive patients following spinal anesthesia were compared hypertension SBP >160mmHg and in the normotensive SBP <160 mmHg. During the study period the bupivacaine were used.

Both of them maximally a significant decrease in SBP when compared to patient baseline values between controlled hypertension and normotensive patients ($p < 0.05$). The mean SBP decreased from 174.4 mmHg to 142.6 mmHg (20.9%) and from 171.5 mmHg to 135.6 mmHg (18.2 %) whereas, in mean DBP decreased from 101.1 mmHg to 76.8 mmHg (21.8%) and 90.8 mmHg to 78.3mmHg (13.8%) in hypertension and normotensive patient respectively. These results shown that, both SBP and DBP expressed minor drop was seen in the normotensive group than the hypertension group with bupivacaine used under spinal anesthesia with $p < 0.05$ (33).

A study done in Malaysia by Poh KS et al, 2007 based on prospective cohort study, comparing the blood Pressure changes between the normotensive and controlled hypertension Patients immediately after spinal anesthesia with in the first one hour surgery and compared the hemodynamic parameter maximal decrease mean SBP from base line was 22.2 (21%) mmHg in the controlled hypertension group and 14.2 (15.4%) mmHg in the normotensive group (34).

On similar pattern a study done in France by Benkhad RA et al, 1989 a total 60 patients on a comparison between normotensive and controlled hypertension patients after spinal anesthesia revealed SBP, MAP and DBP were compared between the two groups. The BP (SBP, MAP and DBP) decrease from the base line value was significantly dropped in controlled Hypertension patients (25%, 27.8%, and 27.5%) than normotensive patients (14.3%, 16.6%, and 12.7%) respectively. The results from the study shows in Controlled hypertension patients was more significant developed of hypotension (the SBP was 30% lower than base line) than normotensive patients ($p< 0.05$) (35).

The results from a study done in Iran by Bashir R et al, 2008 a total of 50 patients on comparison of the hemodynamic response between controlled hypertension and normotensive patients, shown that the incidence of systemic hypotension approaches to 25-82% in both normotensive and controlled hypertension patients. But the incidence of hypotension was lower in normotensive group than controlled hypertension group. Hypotension occurred 9 out of 25 patients (36%) in normotensive patients while in controlled hypertensive group 15 out of 25 patients (60%) was developed hypotension with $p < 0.05$ (36).

A prospective cohort study conducted in India by Dinakar KR et al, 2018 a total of 60 patients on the comparison of hemodynamic response following spinal anesthesia between normotensive and controlled hypertension patients was found that, SBP dropped in both groups and it was fall of BP maximally seen at 10 min post-spinal anesthesia. The fall of mean SBP in both groups was

not statistically significant over the time periods when compared with baseline of the same group as analyzed. From both of them the MAP was a significant drop of more than 30% in controlled hypertension patients (P = 0.04) which shows the incidence of hypotension was significant in controlled hypertension patients. On evaluating the SBP 8 (26.6%) patients in Normotensive and 17 patients (56.6%) in controlled hypertension had a drop of 25% and above from baseline and there was statistically significant difference between Normotensive and controlled Hypertension (P = 0.01). A 25% and above a drop in DBP which was 5 in Normotensive and 9 in controlled Hypertension group respectively. The use of vasopressors in response to hypotension was necessarily 8 in Normotensive and 15 in controlled Hypertension patients. The difference was not statistically significant (P = 0.06). The incidence of bradycardia (HR < 60 bpm) was seen 4 (13.3%) patients in each groups and the rescue therapy was injected atropine in all cases (37).

In another prospective cohort study done in turkey by Acar NS et al, 2013 on comparison of hemodynamic response following spinal anesthesia between controlled hypertension and normotensive patients and it was 60 patients included in the study period. There was no significant difference between the groups with respect to age, sex, weight, height, maximal height of sensory block, the incidence of hypotension, bradycardia and the amount of fluid infused (p>0.05). Later the number of patients who developed the incidence hypotension were (6/30) 20% within 5-40min in the controlled hypertension group and (1/30) 3.3% within 15 min in the normotensive group. The number of patients who were developed bradycardia 6/30 (20%) in the controlled hypertension and 7/30 (23%) in the normotensive group at the time period 5-40 min. over all the results shown that there was no statistically significant difference between normotensive and controlled hypertension patients in the incidence of hypotension caused by spinal anesthesia with 0.5% hyperbaric bupivacaine (28).

In a prospective cohort study conducted by Fukuda T et al, 1988 in Japan on the Comparisons of Tetra Caine Spinal Anesthesia with an adjuvant Clonidine and Phenylephrine in Normotensive and controlled Hypertension patients, there were 75 patients included in the study. The study participants were grouped in to three according to the study design. 9 Controlled hypertension patients were allocated to each groups which was clonidine group (n = 25) received 2 mL of 0.5% tetra Caine 10 mg containing clonidine 0.15 mg; phenylephrine group (n = 25) received 2 mL of 0.5% tetra Caine 10 mg containing phenylephrine 3 mg; and control group (n = 25) received 2 mL of 0.5% tetra Caine 10 mg alone. The result shows, there was no significant

differences among clonidine, phenylephrine, and control groups about the sex, age, height, weight, hemoglobin, plasma sodium, and potassium concentration. Although, the mean values of systolic BP in controlled hypertension patients were higher than normotensive group. The resting BP and HR did not differ significantly among clonidine, phenylephrine and control groups between the Normotensive and controlled hypertension patients. In patients given clonidine the mean arterial pressure (MAP) was approximately 20% ± 10% lower than the resting values, especially for controlled hypertension who received clonidine patients the MAP remained lower for 4-6 h after the injection. It was compared the percentage change of SBP between normotensive and controlled hypertension patients and also there was no significant difference among any of three groups ($p>0.05$) and in addition to that the incidence of hypotension in controlled hypertension was 55.5% and 43.8% in normotensive group (38).

In a prospective cohort study carried out by Rabbani MW et al, 2013 in Pakistan on comparison of hemodynamic response following spinal anesthesia between controlled hypertension and normotensive patients the results shown that, the incidence of hypotension was 17 (34%) out of 50 in normotensive while 31 (62%) out of 50 in controlled hypertension patients. He also reported that the fall of SBP was a statistical significant difference between the two groups after spinal anesthesia. The study reflects also the SBP decreased significantly from the baseline resulted dramatically changes in MAP, SBP and DBP over the time period (14).

A study conducted in Korea, 2013 shown that the level of block ≥ T5 and the age ≥ 40 years are the two main factors to develop hypotensive complication after spinal anesthesia which shows the incidence of hypotension was from 15.3% to 33%. Additionally, they were suggested that for all the age ≥40 patients who are scheduled to undergo surgery under spinal anesthesia they are prone to end up hypotension and also early prediction of hypotension is important for proper anesthetic management (18).

In another study in France on comparing the hemodynamic status after spinal anesthesia between young (< 40 years) and elderly (> 65 years) group shown that a decrease in SBP between 20 % and 30 % persisted for more than 10 min in 1 (3 %) patient in the young group and 11 patients (23%) in the elderly group. despite from the study the mean volume of ringer lactated solution and phenylephrine administered during the first 30 min was significantly greater in elderly group than young group (39).

2.1. Hypotheses

1. **H0:** There is no difference in incidence of hypotension after spinal anesthesia between the controlled hypertension and normotensive groups.

   HA: There is a difference in incidence of hypotension after spinal anesthesia between the controlled hypertensive and normotensive groups.
2. **HO:** There is no difference in the occurrence of bradycardia after spinal anesthesia between the controlled hypertensive and normotensive groups

   HA: There is difference in the occurrence of bradycardia after spinal anesthesia between the controlled hypertensive and normotensive groups.
3. **H0:** There is no difference in variation of mean blood pressure after spinal anesthesia between the controlled hypertension and normotensive groups.

   HA: There is a difference in variation of mean blood pressure after spinal anesthesia between the controlled hypertension and normotensive groups.
4. **H0:** There is no difference on vasopressor consumption between the two groups

   HA: There is a difference on vasopressor consumption between the two groups

2.2. Conceptual Framework

By considering the above review on the hemodynamic status and factors associated with spinal anesthesia induced hypotension and Bradycardia among controlled hypertension and normotensive patients are summarized on the conceptual framework presented below.

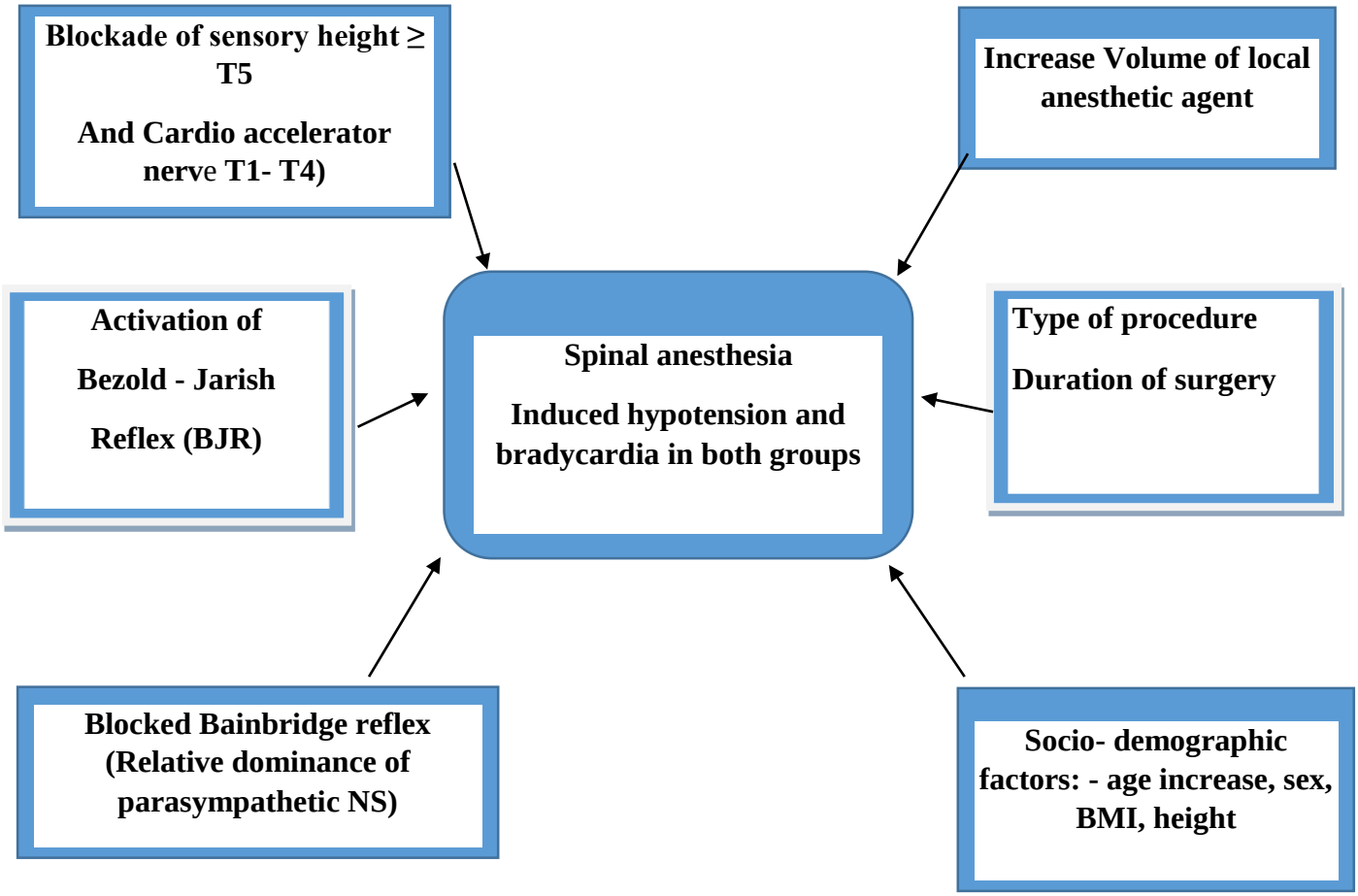

Figure 1: Conceptual framework that shows factors affecting spinal anesthesia induced hypotension and bradycardia to both normotensive and controlled hypertension patients (3, 6, 18, 40 and 41).

3. Objective

3.1 General objective

To compare hemodynamic response following spinal anesthesia between controlled hypertension and normotensive patients undergoing surgery below the umbilicus at Black lion hospital Addis Ababa, Ethiopia, 2020

3.2 Specific objectives

To compare the incidence of hypotension after spinal anesthesia between controlled hypertension and normotensive groups within one hour.

To compare bradycardia after spinal anesthesia between controlled hypertension and normotensive group within one hour.

To compare the mean blood pressure variation after spinal anesthesia between controlled hypertension and normotensive groups within one hour.

To compare vasopressor consumption after spinal anesthesia between controlled hypertension and normotensive groups within one hour

4. Methods and Materials

4.1. Study Area and period

The Study was conducted at black lion hospital (BLH) from urology, orthopedic, Gynecological and General Surgery Operation Theater. Black lion hospital is a federal governmental hospital and found under Addis Ababa University.

It has about 800 beds and 14 operation theatres out of which the two operation theaters are for urology and general surgery, the two rooms for elective orthopedics and one rooms for gynecological surgery procedures. Approximately 7000-9000 patients undergo surgery in a year. This study was conducted from October 30, 2019-January 30, 2020.

4.2 Study design:

Hospital- based prospective cohort study design was employed

4.3 population

4.3.1 Source population

All patients age 40 years and above who presenting for elective surgery below the umbilicus under spinal anesthesia at black line hospital.

4.3.2. Study population

All patients age 40 years and above who presenting for elective surgery below the umbilicus under spinal anesthesia in orthopedic, urology, general and gynecological surgery during the study period at black lion hospital.

4.4. Inclusion and exclusion criteria

4.4.1. Inclusion criteria:

- All elective patients, age 40 years and above who undergo surgery below the umbilicus in the urology, orthopedic, Gynecological and General Surgery under spinal anesthesia were included in the study ("the predication of spinal anesthesia hypotension and getting of high blood pressure in terms of age is ≥ 40 years") (7,17,18)
- American Society of Anesthesiologists Physical status (ASA I & II)
- for controlled hypertension and normotensive patient the heart between 60-100 bpm
- BMI < 30kg/m2 (3,6)
- All patients under spinal anesthesia who received 3ml (15mg) 0.5% hyperbaric

bupivacaine

- For All controlled hypertensive patient are pre-medicate with diazepam at morning

4.4.2. Exclusion criteria:

- Partial spinal block and total spinal
- Heart block greater than first degree, left bundle branch block from ECG interpretation
- New diagnosis of hypertension patient on the day preoperative evaluation and if not optimized or treated with anti-hypertensive agent greater than two weeks.
- Athletics
- The day before operation the long acting antihypertensive agent like; angiotensin converting enzyme inhibitors, diuretics and CCB if not changed by nifedipine.
- Patients who had blood loss necessitating transfusion: multiple trauma and vascular surgery (severely blood loss which could be affect the hemodynamic status of the patient)
- Combinations of spinal block with other type of anesthesia (inhalational or intravenous sedation and general anesthesia).
- Any cardiovascular disease (valvular heart disease, cardiomyopathies etc.), DM, renal failure, anemia, electrolyte disturbance and Pregnancy

4.5. Study variables

4.5.1. Independent variables:

Socio-demographic variables: Age, sex, Weight, Height, BMI, ASA status

Characteristics of CVS condition: History of hypertension, cardiovascular status and base line Hemodynamic

Procedure related variables: Duration of surgery, type of surgery, blood loss during surgery and position

Anesthesia related variables: Amount of fluid intake (preload or co-load), type of local anesthesia, dose of local anesthetics given, anti- hypertensive agent, beta blockers, level of sensory and autonomic block

4.5.2 Dependent variables:

- Hypotension
- Bradycardia
- Mean Blood pressure

- ❖ Vasopressor consumption

4.6. Operational definitions:

Hypotension: SBP ≥ 25% decrease from the base line value of the SBP (13, 14).

Controlled hypertensive: According to the national institute health public, the patient is treated and optimized for ≥ 2 weeks and clinically the BP getting < 140/90 mmHg as a result of treatment by anti- hypertensive medication (28).

Normotensive: According to American medical association, who had not been diagnosed having history hypertension and previously not exposed with anti-hypertensive medication and for the age of < 60 years old as the clinical BP getting < 140/90 mmHg and adult aged 60 years and above the clinical BP getting < 150/90 mmHg (42).

Bradycardia: HR < 60 beats per minute (38)

Baseline value: measurement taken before spinal anesthesia given

The level of sensory block: is loss of sensation for cold water or alcohol and pin prick will be recorded bilaterally in the anterior axillary line or mid-clavicle line

American Society of Anesthesiologists (ASA) physical status classification: developed by the ASA task force which classify patients according to their physical status (systemic well-being)

- ASA class I: normal healthy patient
- ASA class II: Mild diseases or controlled, without functional limitations.

Hemodynamic parameter: BP (SBP, DBP and MAP) and HR

Base line hemodynamic: measuring of blood pressure and heart rate before performing spinal anesthesia.

Autonomic block: blocking of sympathetic nervous system and with their dominating parasympathetic nervous system

4.7. Sample size determination and sampling technique:

4.7.1. Sample size determination

Sample size was determined by using Epi-info 7 statistical calculator for independent cohort and considering one to one ratio of the controlled hypertension were exposed with anti-hypertensive medication and unexposed in normotensive groups and rechecked by manual calculation using double population proportion for comparison. by considering a power of 80%, confidence interval 95% and ratio of normotensive to controlled hypertension patients 1:1 and incidence of hypotension in normotensive patient were not exposed to anti-hypertensive medication =34%

and incidence of hypotension in controlled hypertension were exposed to antihypertensive agent = 62%, which is estimated from previous study done in Pakistan (14). A sample size of 50 patients were needed per group. Adding 10% for non-response and the total sample size was 110 (55 subject to each group)

$n1 = \frac{(Z1+Z2)^2 pq(r+1)}{r(P1-P2)^2}$…….. n_2 = r n1

$p = \frac{P1+P2}{r+1}$……..q=1-p

n_1= number of normotensive patients were not exposed to anti-hypertensive agent

n_2= number of controlled hypertensive patients were exposed to anti-hypertensive agent

Z_1= 1.96 = value of the standard normal distribution corresponding to a significance level of α (1.96 for a 2-sided test at the 0.05 level)

Z_2= 0.84 = value of the standard normal distribution corresponding to the desired level of power (0.84 for a power of 80%)

P_1=proportion of normotensive patients previously developed hypotension and who were not exposed with anti-hypertensive agent and q1 = 1-p_1

P_2= proportion of controlled hypertension patients previously developed hypotension and who were exposed to anti-hypertensive agent and q_2 = 1-p_2

r = ratio of non-exposed (normotensive) to exposed (on anti-hypertension agent)

p_1 = 0.34 and **p_2** = 0.62, **r**=1

$p = \frac{P1+rP2}{r+1} = \frac{0.34+ (1x0.62)}{1+1} = \frac{0.96}{2}$, **p=0.48** and then **q** = 1-p=1-0.48

q=0.52 ; $n1 = \frac{((1.96+0.84)^2 \text{ x } 0.48 \text{ x } 0.52\ (1+1))}{1(0.34-0.62)^2} = \frac{3.913728}{0.0784}$

n_1 = 49.92 ≈ 50 patients needed for normotensive cases and again for the controlled hypertensive patients below as follow's

n_2 = nr1 (50x1) and then **n_2 = 50** needed for controlled hypertensive patients

Desired sample size = adding 10% for non-response it becomes a total of **110 or 55** subjects to each group was included in this study.

4.7.2. Sampling technique

Participants were selected using Systematic sampling technique. The number of participants selected from each operational theater based on population proportion size. The operational theaters in orthopedic, urology, general and gynecological surgery were included in this study.

These operational theater were selected because under spinal anesthesia below umbilical surgery were provided in these operational theaters.

The registration book showed that at 3 month a total of 292 elective cases were operated at black lion hospital from urological (84), orthopedic (112), gynecological (48) and general surgery (48) under spinal anesthesia. According to this data the patients were grouped in to four Operation theater based on the population proportion allocation.

In orthopedic operation theater $\frac{(112)x100}{292}$ =38.35% of patients were operated and the sample required 0.3835x110=42

In urology operation theater $\frac{(84)x100}{292}$ =28.76% of patients were operated and the sample required 0.2876x110=32

In gynecological $\frac{(48)x100}{292}$ =16.43% of patients were operated and the sample required 0.14x110=18

In general surgery $\frac{48x100}{292}$ =16.43% of patients were operated and the sample required 0.1643x110=18

So sample interval (K) was calculated from each specialty surgery as K = $\frac{N}{n}$

The Kth value in both general and gynecological surgery K = $\frac{48}{18}$ =3 and also similar the Kth value in orthopedic $\frac{112}{42}$ =3 and urology surgery $\frac{84}{32}$ =3

1st participant was selected from the first three list of participants using lottery method, then every 3rd patients from each specialty surgery were included in this study from daily scheduled lists until to end up with a total 110 sample size. The daily operation schedule lists was used as a sampling frame.

The day before operation in the waiting room the anesthetist was checked all exposed group under nifedipine and antianxiety ordered. Every selected participant after then placed to either group based on the exposed or unexposed or whether they are normotensive or controlled hypertension. The selected participant were received fluid co-load with 15ml/kg crystalloid solution during spinal anesthesia performing to prevent intraoperative hypotension and followed for one hour after spinal anesthesia.

4.8. Data collection methods

4.8.1. Data source, data collection tools, procedure and personnel

The data structured questionnaire was prepared in English. The structured questionnaire has six parts.

The first part contains general information contains socio-demographic characteristics of the subjects, the second part contains type of monitored used, the three part contains preoperative assessment, the 4th part consists of intraoperative assessment, the 5th part contain of rescue medication and the 6th part contains intraoperative vital sign before and after spinal anesthesia administered. The questionnaire was adapted from different articles with some modification (28, 35, 36 and 37).

The data collection was done by four Anesthetists and supervised by one anesthetists that have experience in research. The patients' socio demographic data (age, sex, weight, height, BMI, ASA status, duration of hypertension), type of procedure, duration of surgery, amount of blood loss, anti-hypertensive agent, total fluid infused intraoperative and peak level of sensory block were recorded.

Baseline blood pressure (SBP, MAP and DBP) using noninvasive blood pressure (NIBP) and heart rate (HR) using pulse oximetery were measured in the 1st one minute and later 2 min before spinal anesthesia performing in the operation room table and record averagely. Continued After spinal anesthesia performed were measured at 1, 3, 5, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55 and 60 min- after then, the level of sensory block sensation was evaluated with cold alcohol and pin prick after spinal anesthesia.

4.9. Data quality control

To ensure the quality of data the following measure should be under taken

The questionnaire was adapted from different articles with some modification and checked by anesthesia professional experts' and advisors whether the adapted questionnaire measure the expected goal. After feedback obtained from experts, the questionnaire was rewritten accordingly.

A total of one day training was provided to the data collectors and supervisors about the check list how to record properly. The training was focuses mainly on how to record properly on each part of the questionnaire and how to approach with patient during data collection.

Pre-test of the questionnaire have been performed with 5% of the total sample size at Menelic II referral hospital.

The principal investigator and supervisors were made daily supervision during the whole period of data collection.

Every day the questionnaires are reviewed and checked for Completeness, clarity and consistency by supervisors and investigator.

4.10. Data processing and analysis

The Data were checked by manually for completeness and then entered and cleaned using Epi Info version 7 and exported to Statistical package for Social Sciences (SPSS) software version 20. Continuous data were tested for normality by using Shapiro wilks-test with $p>0.05$ and histogram with superimposed curve and we have used levene's test to check the homogeneity of variance ($p>0.05$).

Descriptive data were described in mean ± SD for normally distributed and median and Interquartile range for non-normally distributed data. Comparison of numerical variables between the study groups age, body weight, height, BMI and hemodynamic parameters, blood loss and fluid management with respect to normal distribution were analyzed using independent sample t- test and level of sensory block with respect to non -normally distributed were analyzed using Mann -Whitney U test.

For SBP hypotension reading, the percentage change from base line was computed using the formula**:**

$$\boldsymbol{SBP}\% = \frac{(\textbf{Baseline SBP} - \textbf{SBP at each time record after SA})\textbf{x100}\%}{\boldsymbol{Baseline\ SBP}} \quad (34)$$

N.B. SBP decreased from base line b**y ≥ 25%** considered to be hypotension

Categorical variables between the study group's sex, occurrence of incidence hypotension, bradycardia and vasopressor consumption were compared with the chi-square test. Statistically Significance was determined at P value < 0.05.

4.11. Ethical consideration

Ethical clearance letter was obtained from the Institution Review Board of the Addis Ababa University, Institution of school of medicine, Anesthesia department. Permission to conduct the research was obtained from the hospital medical directors. We have used Amharic language for providing sufficient information to each participant, about the purpose of the study, the right to with draw, the right to participated or not. Individual acceptance written consent were obtained from each participant before the data collection. Finally the study was never disclose any information by the name of participants to assure confidentiality.

5. Results

Characteristics of demographic data and comparison of the groups

A total of 110 (55 controlled hypertension and 55 normotensive) patients below the umbilical surgery under spinal anesthesia were included in this study. Demographic characteristics did not differ statistically significant between the two groups and Peak level of sensory block ($P > 0.05$). Both groups were comparable in terms of demographic and peak level of sensory block.

Table 1: Comparison of demographic data between the two groups: At Black Lion hospital from October 30, 2019-January 30, 2020.

Variables		**CH (n= 55)**	**N (n= 55)**	**P- value**
Age in years (**Mean ± SD)***		58.15 ± 10.662	60.78 ± 11.832	.222
Sex	M [f (%)]	40 (72.7%)	48 (87.3%)	.095
	F [f (%)]	15 (27.3%)	7 (12.7%)	
Weight in Kg (**Mean ± SD)***		66.4364±5.88395	65.2727±7.10361	.352
Height in cm (**Mean ± SD)***		167.0364±3.91561	166.4909±4.96235	.524
BMI in Kg (**Mean ± SD)***		23.9244 ±2.55949	23.5787±2.58013	.482
Peak level of sensory block **		T10 (T6-T10)	T10 (T6-T10)	.557
Anti- Hypertensive medication (n)				
	Calcium channel blockers	33	Nil	
	Diuretics	4	Nil	
	ACI inhibitors	15	Nil	
	ACI inhibitors & beta-blockers	3	Nil	
	Nifedipine morning dose (mg)	20-30	Nil	
Morning anti- anxiety (diazepam)		0.15-0.2 mg/kg	Nil	
Duration of hypertension (years)		1-6	Nil	

Data are given as (Mean ± SD)*: independent sample t test*, [median (IQR)] **: Mann -Whitney U test, f: frequency

Comparison of base line hemodynamic parameter, blood loss and intraoperative fluid management

There was no difference on the usage of Bari-city of LA, volume of local anesthetics, Gouge of spinal needle used, time of LA administered in to CSF and vertebral interspace drug administration between the two groups **(Table 2)**.

Base line hemodynamic parameter, fluid co-load and total IV fluid used intraoperative, blood loss with in the first one hour and duration of surgery did not differ statistically significant between two groups. Both groups were comparable in terms of baseline hemodynamic, fluid co-load, total IV fluid infused intraoperative, blood loos and duration of surgery (**Table 2)**.

Table 2: Comparison of base line hemodynamic parameter, Blood loss and intraoperative fluid management between the two groups: At Black Lion hospital from October 30, 2019-January 30, 2020.

Variables	CH(n=55) Mean ± SD	N (n= 55) Mean ± SD	P-value
Baseline SBP (mmHg)*	132.8909±4.57721	133.9455±5.66803	.285
Baseline DBP (mmHg)*	78.5455±7.726380	79.0182±7.80430	.750
Baseline MAP (mmHg)*	91.2909± 5.108720	93.5273±6.75731	.053
Baseline HR (bpm)*	78.2545±9.3238400	76.5636±10.34903	.370
Fluid co-load (ml)*	990.0000±83.555260	981.8182±107.30867	.656
Total fluid infusion at 1sthr.(ml)	2176.3636±482.26458	2129.0909±485.97848	.610
Duration of surgery (min)*	34.2545±4.3470600	34.0545±4.09344	.840
Time of LA administered in to CSF (in second)*	16.7273±2.3994900	16.4545±2.29184	.543
Blood loss (ml)*	218.9091±107.64607	215.8182±83.12621	.866

SBP: systolic blood pressure, DBP: diastolic blood pressure, MAP: mean arterial pressure, HR: heart rate *: independent sample t test

Comparison of mean systolic blood pressure

There was a statistical significant difference in mean systolic blood pressure value between the controlled hypertension (CH) and normotensive (N) group when compared with base line in the same group at the measurement of 15^{th,} 20th, 25th and 30th minute with p value (p= 0.025, 0.009,

0.009, 0.002 respectively) **(Table 3)**. As compared to the baseline, mean systolic blood pressure was significantly low in the controlled hypertension (CH) group with the lowest mean of SBP 116.5818 mmHg and 116.3455 mmHg at the measurement of 25th and 30th minute respectively. Although in normotensive (N) group all the mean SBP records were also lower than base line at all measurement after spinal anesthesia over the time period **(Table 3)**.

Table 3: comparison of mean systolic blood pressure between two groups: At Black Lion hospital from October 30, 2019-January 30, 2020

Variables	CH (n=55) Mean ± SD	N (n=55) Mean ± SD	P- value
Baseline SBP	132.8909 ± 4.57710	133.9455±5.668030	.285
SBP at1min	131.0182±9.066610	128.4000±10.92161	.174
SBP at 3min	126.8000±12.07753	127.7636±10.59518	.657
SBP at 5min	123.5636±10.96926	125.8909±11.43366	.278
SBP at 10min	120.7818±11.18148	124.4727±12.20633	.101
SBP at 15 min	118.8727±12.66967	124.1455±11.61005	.025
SBP at 20 min	117.4182±12.92814	123.6727±11.81031	.009
SBP at 25min	116.5818±13.30927	123.0000±12.12436	.009
SBP at 30min	116.3455±11.94310	123.5818±11.54811	.002
SBP at 35 min	117.8909±11.07997	122.0727±12.54452	.067
SBP at 40min	118.0727±12.66499	122.3818±12.28895	.073
SBP at 45min	119.2727±12.73586	122.2364±11.53572	.204
SBP at 50min	121.0000±11.60460	123.3818±11.37165	.279
SBP at 55min	122.3455±10.17662	124.5818±11.18811	.275
SBP at 60 min	125.1091±8.499830	126.7818±9.425520	.331

SBP: systolic blood pressure, SD: standard deviation, *: independent sample test

Systolic blood pressure (SBP)

The mean SBP was 132.8909 mmHg and 133.9455 mmHg in the group CH and N group respectively at base line before the patient was administered spinal anesthesia. The SBP was dropped in both groups after spinal anesthesia **[figure 1].** The maximal fall of mean SBP was

seen from **132.8909** mmHg to **116.5818** mmHg (12.3%) and **116.3455** (12.45%) mmHg at 25 min and 30 min in CH group and from **133.9455** mmHg to **122.0727** (8.9%), **122.3818** (8.6%), **122.2364** (8.7%) mmHg at 35min, 40 min and 45 min in N group respectively. The increase in SBP following the maximal drop was seen to a greater degree in **CH** group than **N** group.

The insignificant result after 35 minutes may be the hypotensive episodes could be effectively managed without any serious hazards to the patient.

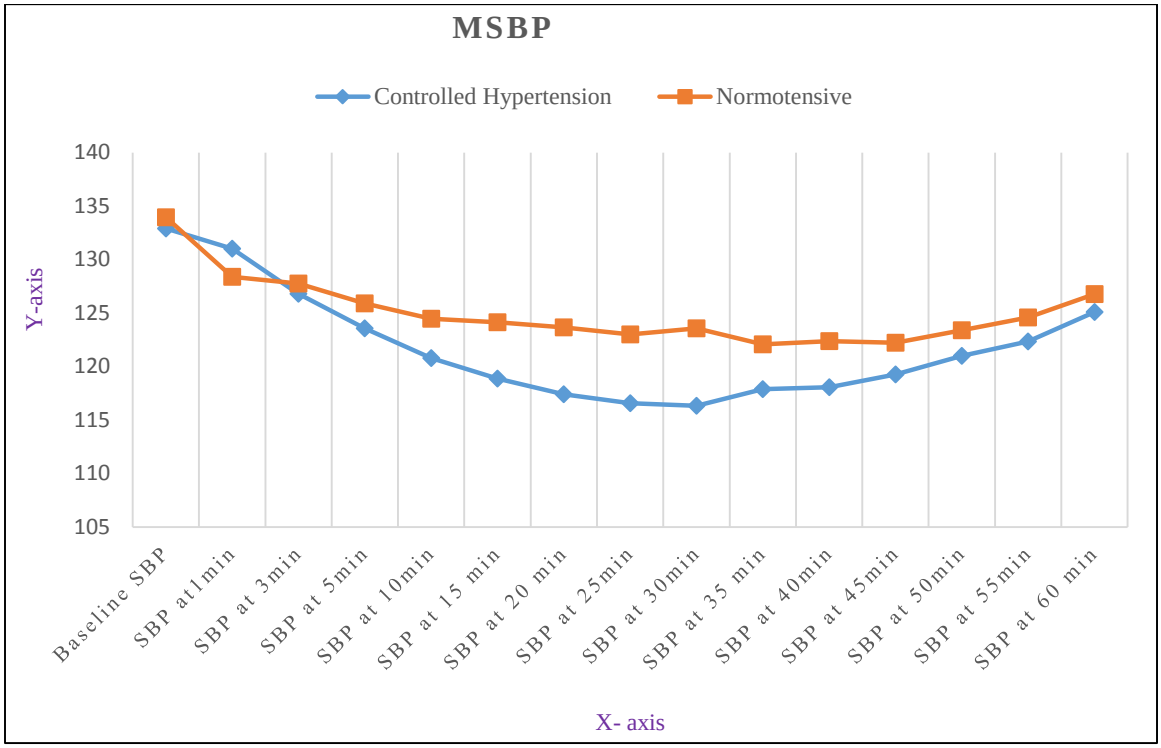

Figure 1. Variation in the systolic blood pressure (SBP) between two groups. The changes from base line of the SBP in the first one hour in post spinal anesthesia. X- Axis duration and y-Axis mean of SBP in mmHg. At Black Lion hospital from October 30, 2019-January 30, 2020.

Comparison of mean diastolic blood pressure

The mean diastolic blood pressure was comparable between the two groups**.**

The fall of DBP between CH and N group was not statistically significant difference over the time period when compared with the base line of the same group (**Table 4**).

As compared to the baseline, the mean diastolic blood pressure record was higher than the baseline in controlled hypertension (CH) group at the measurement of 1st and 60th minute. While

in the normotensive (N) group, all the mean value of diastolic blood pressure was lower than baseline at the measurement in the first 1 hour **(Table 4)**.

Table 4: comparison of mean diastolic blood pressure between two groups: At Black Lion hospital from October 30, 2019-January 30, 2020

Variables	CH (n=55) Mean ± SD	N (n=55) Mean ± SD	P- value
Baseline DBP	78.5455±7.72638	79.0182±7.80430	.750
DBP at 1 min	79.8364±8.51744	78.0364±8.43486	.268
DBP at 3 min	77.5091±11.44855	76.7636±8.51353	.699
DBP at 5 min	76.6182±10.83289	75.7455±8.10856	.633
DBP at 10min	76.6364±10.47283	76.0545±8.45997	.749
DBP at 15 min	75.0000±9.81118	75.6909±8.42147	.693
DBP at 20 min	75.4727±11.06522	76.0909±9.74161	.756
DBP at 25 min	73.8909±9.61032	74.7455±10.09440	.650
DBP at 30 min	74.9091±10.44256	74.5455±9.04888	.846
DBP at 35 min	75.9091±9.16166	74.5455±9.45911	.444
DBP at 40 min	75.2909±8.97460	75.2909±10.06952	1.00
DBP at 45 min	76.3273±9.26374	76.3636±9.66353	.984
DBP at 50 min	77.0182±9.44867	76.6182±9.02566	.821
DBP at 55min	78.0727±9.52551	77.4000±8.94551	.703
DBP at 60 min	79.3818±8.4762	76.6182±8.22872	.101

DBP: diastolic blood pressure, SD: standard deviation, *: independent sample t test

Diastolic blood pressure (DBP)

The mean DBP was **78.5455 mmHg** and **79.0182 mmHg** in CH and N group at base line, before the patient administered spinal anesthesia **[figure 2].** The mean DBP was dropped after spinal anesthesia and fall was maximally seen from **78.5455 mmHg** to **73.8909 mmHg** (5.9%**)** at 25 min in CH groups and from **79.0182 mmHg** to **74.7455** mmHg (5.4%)**,74.5455** mmHg (5.7%) and **74.5455** mmHg (5.7%) at 25th, 30th and 35th min was also dropped in N group. The mean DBP increase following maximally drop was seen in the **CH** group and **N** group in post - spinal anesthesia in the first 1 hour.

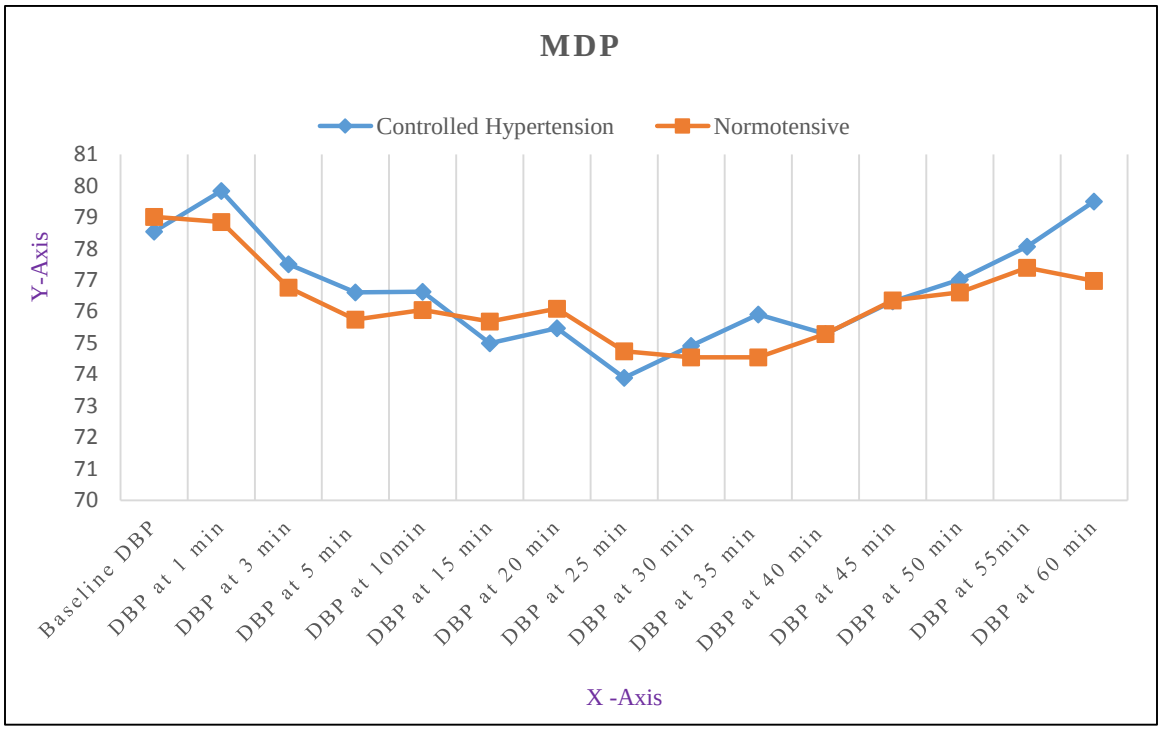

Figure 2. Variation in the diastolic blood pressure (DBP) between two groups. The changes from base line of the mean DBP in the first one hour in post spinal anesthesia. X- Axis – duration and y-Axis mean of DBP in mmHg. At Black Lion hospital from October 30, 2019-January 30, 2020.

Comparison of mean MAP

There was statistical significant difference between the controlled hypertension (CH) and the Normotensive (N) group at the measurement of 20th, 25th and 30th minute (p= 0.004, 0.003, 0.039 respectively). As compared to the base line, mean of MAP record was lower than baseline in both groups in each time interval within one hour **(Table 5)**.

Table 5: comparison of mean MAP between two groups: at black lion hospital from October 30, 2019-January 30, 2020

Variables	CH (n=55) Mean ± SD	N (n=55) Mean ± SD	P- value
Baseline MAP	91.2909±5.10872	93.5273±6.75731	.053
MAP at 1 min	90.2364±8.18527	90.7818±8.71077	.736
MAP at 3 min	88.7455±8.91569	90.1636±9.12620	.412
MAP at 5min	86.8000±10.71586	90.4364±9.83148	.066
MAP at10 min	86.5818±9.38417	89.4545±9.15670	.107
MAP at 15min	85.8909±9.40778	88.8545±8.91195	.093
MAP at 20min	84.7091±9.18064	90.2364±10.56368	.004
MAP at 25min	83.5091±8.97708	88.9636±9.65126	.003
MAP at 30min	84.4909±9.48854	88.2364±9.30544	.039
MAP at 35min	85.1091±9.27895	87.7818±9.28099	.134
MAP at 40min	84.6909±8.64928	87.9636±9.22951	.058
MAP at 45min	85.4364±8.24343	87.7636±8.46991	.147
MAP at 50min	85.6364±7.75639	87.5273±9.48850	.255
MAP at 55min	86.5636±7.74779	87.5273±9.18706	.553
MAP at 60min	88.0364±7.67141	88.200±9.27042	.920

MAP: mean arterial pressure, SD: standard deviation, *: independent sample t test

Mean arterial pressure (MAP)

The changes seen in the MAP drop was similar to the SBP. The base line MAP was **91.2909 mmHg** and **93.5273 mmHg** in **CH** and **N** group respectively. The mean MAP was fall following spinal anesthesia over the time period **[figure 3]**. The maximal fall of MAP was seen from **91.2909 mmHg** to **83.5091 mmHg** (8.5%) at 25 min in the **CH** group and from **93.5273 mmHg** to **87.5273mmHg** (6.4%) at 50min and 55 min in the **N** group. The mean MAP increase following maximally drop was seen to a greater degree in the **CH** group than **N** group in post-spinal anesthesia in the first 1 hour.

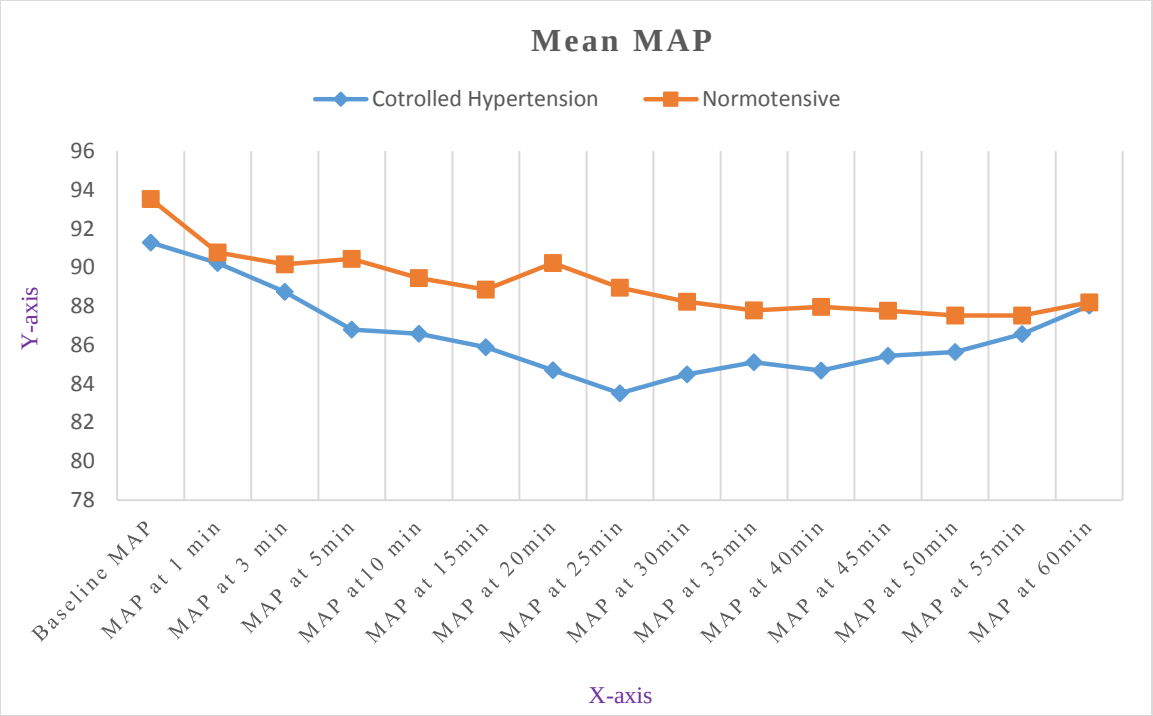

Figure 3.Variation in the mean arterial pressure (MAP) between two groups. The changes from the base-line of the MAP in the first one hour in post-spinal anesthesia. X- Axis-duration and y-Axis mean of MAP in mmHg. At Black Lion hospital from October 30, 2019-January 30, 2020.

Comparison of mean heart rate

There was a statistical significant difference in mean heart rate between controlled hypertension (CH) and normotensive (N) group at the measurement of 3rd minute (p=0.023) **(Table 6)**.

As compared to the base line, the mean record of heart rate in controlled hypertension group was higher than baseline with the highest value to be **78.6364 mmHg** and **79.4364 mmHg** at the 1st and 3rd minute. While in the normotensive group, all the mean record of HR was lower than base line at each time interval with in the first 1 hour **(Table 6)**.

Table 6: comparison of mean heart rate between two groups: At Black Lion hospital from October 30, 2019-January 30, 2020

Variables	CH (n=55) Mean ± SD	N (n=55) Mean ±SD	P value
Baseline HR	78.2545±9.32384	76.5636±10.34903	.370
HR at 1 min	78.6364±9.83825	76.2364±11.03188	.231
HR at 3 min	79.4364±10.56157	74.4545±12.03516	.023
HR at 5 min	76.9091±9.96154	74.4364±10.80940	.215
HR at 10 min	75.8545±9.24245	74.2182±11.16491	.404
HR at 15 min	74.2545±9.20390	73.2545±11.40373	.614
HR at 20 min	74.4000±10.60852	73.1636±11.71698	.563
HR at 25 min	74.9818±9.38969	72.7636±11.11216	.261
HR at 30 min	74.2000±9.43084	72.9636±10.28837	.513
HR at 35 min	73.8909±8.91456	73.2000±10.10574	.705
HR at 40 min	74.6909±8.82730	73.1091±8.61883	.344
HR at 45 min	74.9636±8.17395	72.8909±8.05691	.183
HR at 50 min	74.5273±8.05733	73.8364±7.62249	.645
HR at 55 min	76.6182±8.04269	74.2727±8.27189	.135
HR at 60 min	75.5636±7.22589	74.7636±8.43046	.594

HR: heart rate, SD: standard deviation, *: independent sample t test

Mean heart rate (MHR)

The mean HR at the baseline was **78.2545 mmHg** and **76.5636 mmHg** in **CH** and **N** group respectively. The maximal drop of mean HR from **78.2545 mmHg** to **73.8909 mmHg** (5.6%) at 35 min in **CH** group and **76.5636 mmHg** to **72.7636 mmHg** (4.96%) at 25 min in **N** group **[figure 4]**. The increase in mean heart rate following maximally drop was seen to a greater degree in CH group than the N group after spinal anesthesia.

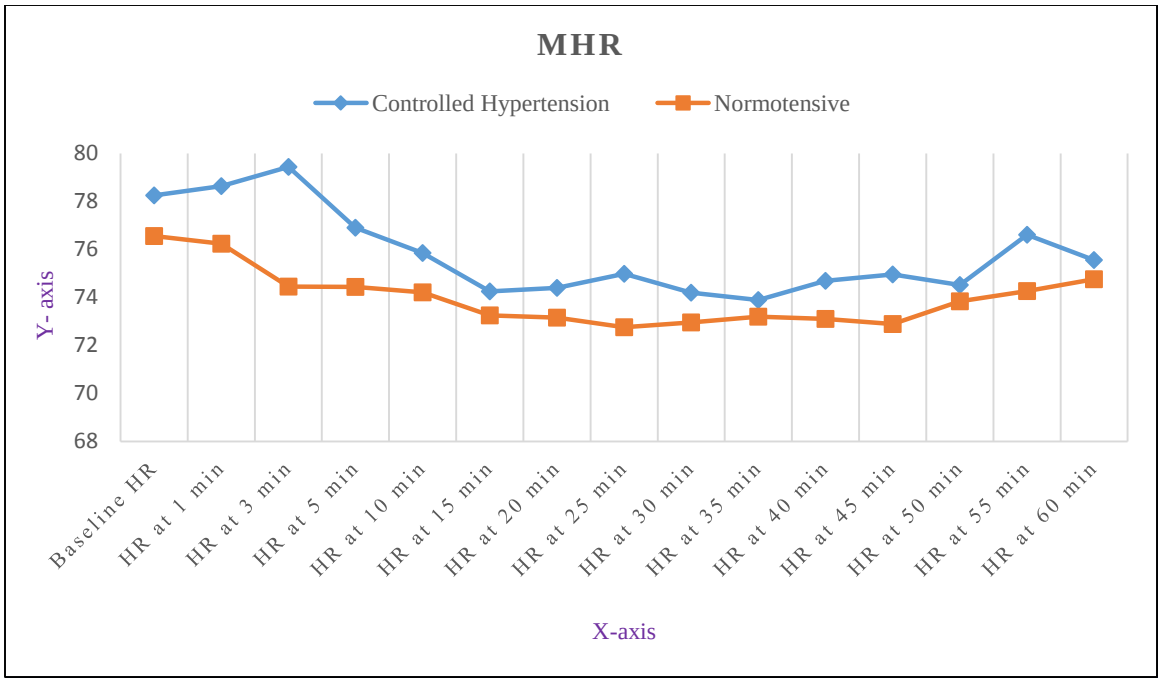

Figure 4. Variation in heart rate (HR) between two groups. The changes from base-line of the HR in the 1st one hour in post- spinal anesthesia. X-axis- duration and y-axis- mean of heart rate in beat per minute. At Black Lion hospital from October 30, 2019-January 30, 2020.

Comparison of the incidence of hypotension and bradycardia

The total number of patient that had a significant decrease of ≥25% of SBP from baseline was 13 (23.6%) and 4 (7.3%) in group CH and N respectively. There was statistically significant a p value 0.018 showing that, the incidence of hypotension was significantly seen in controlled hypertension patients who were regularly on anti- hypertensive medication and continued Nifedipine on the day of surgery **(Table 7)**.

The occurrence of bradycardia (HR<60 b/min) was seen 7 patients in each of both groups and the rescue medication of atropine was injected in all cases. There was no statistically significant difference between CH and N group on dropping the heart rate after spinal anesthesia ($p > 0.05$) **(Table 7)**.

Comparison of vasopressor consumption

The use of vasopressor in response to hypotension was seen essentially 11 (20%) in CH and 3 (5.5%) N group. There was a statistically significant ($p = 0.022$). The increase in vasopressor requirement in response to hypotension was seen to a greater degree in the controlled

hypertension group than the normotensive group (**Table 7)**. The use of total IV infusion with in the first1 hour in the mean value was **2176.3636** ml in **CH** and **2129.0909** ml in **N** group and there was no a statistically significant (p = 0.610) **(Table 2)**.

Table 7: comparison on incidence of hypotension, bradycardia, vasopressor consumption and atropine usage in response to bradycardia between two groups: At Black Lion hospital from October 30, 2019-January 30, 2020

Parameter	CH (n=55)	N (n=55)	P value
SBP within ≥25% drop n (%) (hypotension)	13 (23.6%)	4 (7.3%)	0.018
Vasopressor consumption n (%) (Phenylephrine (50-100µg))	11 (20%)	3 (5.5%)	0.022
Bradycardia n (%)	7 (12.72%)	7 (12.72%)	>0.05 (Ns)
Atropine n (%)	7 (12.72%)	7 (12.72%)	>0.05 (Ns)

Chi-square test with p < 0.05 considered to be statistical significant, Ns: non-significant, SBP: systolic blood pressure, DBP: diastolic blood pressure, MAP: mean arterial pressure

The overall occurrence of hypotension in SBP using independence chi-square test analysis with a Pearson chi-square test showed that there is an association between the controlled hypertension and vasopressor consumption, $\chi 2$ (1, n =110) =5.636, p =0.018) and $\chi 2$ (1, n =110) =5.238, p =0.022) respectively.

Hypotension- SBP decrease of ≥ 25% from base line, bradycardia (HR < 60 bpm) and total vasopressor consumption shows in **(figure 5)**.

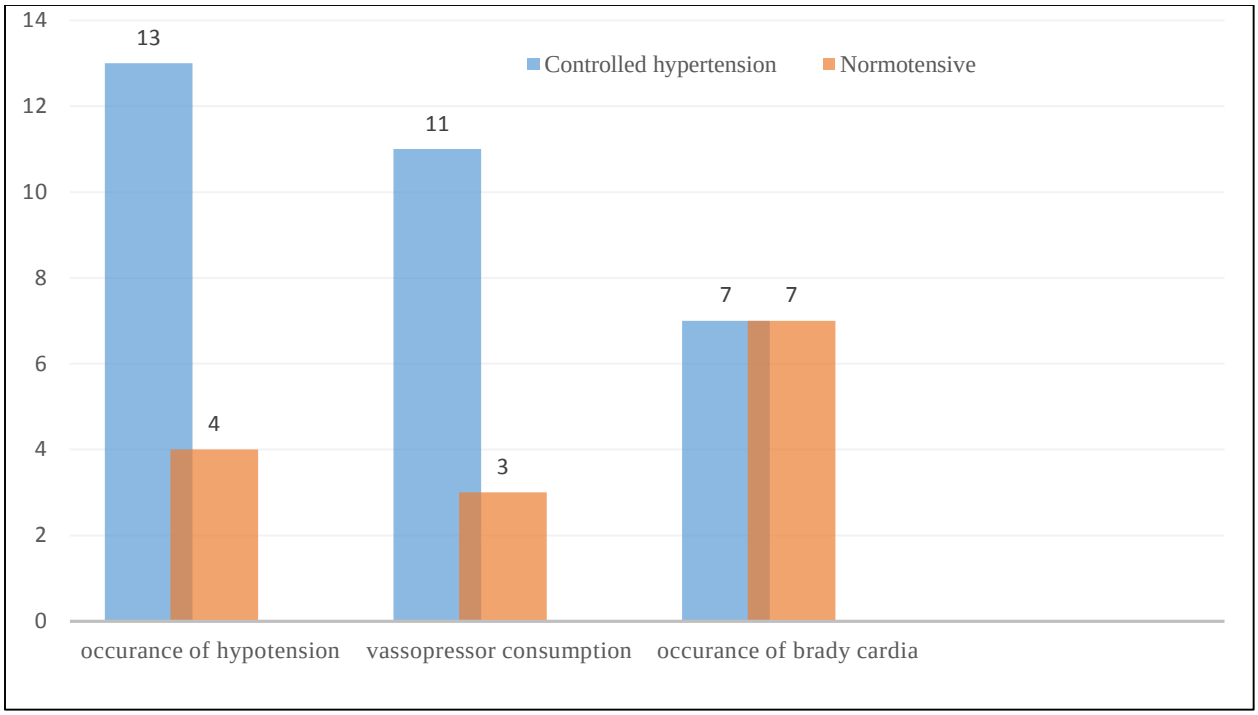

Figure 5: The occurrence of hypotension in SBP, bradycardia and total usage of vasopressor with in the first one hour after spinal anesthesia: At Black Lion hospital from October 30, 2019-January 30, 2020.

6: Discussion

The present study showed that during spinal anesthesia, the incidence of hypotension occurrence in controlled hypertension group was higher than the normotensive group. Hypotension defined as systolic blood pressure decreased by 25% and more than from base line (**29**). This is the most significant predicators of morbidity and patient cardiac events. The current study shows a statistically significant difference in the incidence of hypotension between controlled hypertension and normotensive group.

The result now provides evidence to a significant fall SBP in patient with controlled hypertension when compared to patients with normotensive group. This study showed that the SBP had a drop of 25% and more than from the base- line was seen 23.6% in controlled hypertension and 7.3% in the normotensive group. This was statistically significant difference between the two groups (p=0.018). In this result should considered to be principles for rescue medication. About 11(20%) in group Controlled hypertension and 3(5.5%) patients in group normotensive received phenylephrine in response to a significant hypotension. The need for vasopressor support was statistically significant difference between two groups (p=0.022) **(figure 5).** The difference in the vasopressor consumption among groups was statistically significant probably indicating the incidence of hypotension intraoperative was high in controlled hypertension than the normotensive group due to continued nifedipine on the day of surgery under spinal anesthesia.

The result of this study showed that the incidence hypotension was 13 (23.6%) in controlled hypertension and 4 (7.3%) in normotensive patients which is a statistically significant (p-value 0.018). this finding is consistent with the study done in India which was on comparison of hemodynamic response following spinal anesthesia between normotensive and controlled hypertension patients and found that the incidence of hypotension was 8 (26.6%) in Normotensive and 17 (56.6%) in controlled hypertension patients had a drop of SBP 25% and above from baseline and there was a statistically significant difference between Normotensive and controlled Hypertension (P=0.01). In addition to that our finding regarding to the vasopressor requirement in response to hypotension was received 20% in controlled hypertension and 5.5% in normotensive group which is statistically significant with p-value 0.022. This finding is contrary with the study done India on comparison of vasopressor

consumption 8 (26.6%) in Normotensive and 15 (50%) in controlled Hypertension patients which is not statistically significant (P- value 0.06) (37).

On similar prospective cohort studies, Rabbani MW et al, 2013 reported that, hypotension due to spinal anesthesia as our finding, that the incidence hypotension was 17 (34%) in normotensive and 31(62%) in controlled hypertension was statistically significant with p value < 0.05. This study was also consistent with our finding (14). A possible explanation for the increased incidence hypotension in controlled hypertension than normotensive group could be in hypertensive patients have increased sympathetic activity and norepinephrine level as well as decreased parasympathetic activity and persistent sympathetic stimulation in dependent hypertension itself it causes loss of elasticity in the arterial wall and induces structural changes that in turn results decrement blood pressure due to sympathetic blockade by spinal anesthesia and continue nifedipine on the day of surgery (10).

In contrast to our results, Acar NS et al, 2013 reported that hypotension due to spinal anesthesia in incidence of hypotension between controlled hypertension and normotensive patients was not a statistical significant (p >0.05). The incidence of hypotension was 20% (6 out of 30) in controlled hypertension and 3.3% (1 out of 30) in normotensive group. This study which was contrary to our finding. Over all the current finding did not support the study done in turkey regarding to the occurrence of hypotension between the controlled hypertension and normotensive group under spinal anesthesia (28).

On the other hand one a similar studies which was 1 or 2 decades older than ours, as in our study, that the incidence of hypotension between controlled hypertension and normotensive was different. However, the incidence of hypotension was 55.5% and 43.8% respectively and also there was no a statistically significant (p > 0.05). This older study was also contrary to our finding (38). The inconsistent result may be due to the different technique of monitored used.

In another the current finding showed, the number of patients who developed bradycardia 7 patient in each group which is 12.7% and there was no statistically significance difference between two groups (p >0.05). Those who developed bradycardia was consider criteria for rescue medication, atropine was administered to each groups. One another study Showed (Dinakar KR et al, 2018) as in our study that the occurrence of bradycardia in both groups was not different. The occurrence of bradycardia was 4 (13.3%) patient in each group. so this study

showed, which is consistent with our finding. The variation in percentage between the current studies with other studies may be due to the difference in study design used (**37)**.

In another study showed, the occurrence of bradycardia 6 (20%) in controlled hypertension and 7 (23.3%) in normotensive patients which was consistent with our finding. On the basis of the , current result there is no statistically significant difference between controlled hypertension and normotensive group on the occurrence of bradycardia after spinal anesthesia with p- value > 0.05 (28).

The patients in the studies of Sakic K et al (33) was1or 2 decades older than ours. However, the maximal decrease of mean SBP was 20.9% and 18.2 % whereas in mean DBP decreased (21.8%) and (13.8%) in controlled hypertension and normotensive patient respectively. which was similar to our finding. The difference in percentage may be due to the difference in base line measurement used

The maximal drop of mean SBP was seen 12.3%, 12.45% at 25min and 30 min in the **CH** group and at 35min 8.9%, 40min 8.6% and at 45min 8.7% in the **N** group respectively, where the drop of mean SBP in the CH group was higher than normotensive group. In mean SBP between two groups was Statistically significant seen at 15min, 20min, 25min and 30min (p=0.025, 0.009, 0.009, 0.002). Possible reason for non-significant after 30 min may be the episode hypotension could be effectively managed without serious hazard to the patient. Still no known investigated fully to have any clinical implication on dropping of mean SBP cause detrimental effect on organ system and did not warrant a rescue therapy.

Normally, systolic blood pressure should not drop more than 10 mm Hg. If SBP drop from resting/base line SBP, organ will not adequately perfused and contributed to suffer ischemic damage and/ or be unable to perform adequately. Poor brain blood flow can cause declining mental status, lethargy, somnolence and even coma and also poor renal perfusion may cause renal failure with wide- ranging metabolic consequences (45).

The maximal fall of mean DBP was seen 5.9 % at 25min in the CH group and 5.4%**,** 5.7%, 5.7% in N group at 25min, 30min and 35 min respectively and there was no statistically significant difference between the two groups at all measurement over the time period (p>0.05) **(figure 2).** Usually diastolic blood pressure should remain unchanged or rise slightly. The exact DBP threshold remains has been widely debated or unclear. Further, whether this threshold differs in

patients with obstructive coronary disease who may be vulnerable to reduced coronary perfusion during diastole is a point of debate (46).

The maximal drop of mean MAP was seen 8.5% at 25 min in CH group and consequently 6.4% at 50 min and 55 min in the N group. There was statistically significant difference between two groups (p= 0.004, 0.003, 0.039) at 20^{th}, 25^{th} and 30^{th} min under spinal anesthesia **(figure 3).** The insignificant after 30 min which could be treated effectively with crystalloid solution and vasopressor medication. If MAP drops below the point of 60 mmHg for an extended period, end organ manifestation such as myocardial ischemia and infarction can occur. If the MAP drops significantly blood will not be able to perfuse cerebral tissues, there will be a loss of consciousness, and neuronal death will quickly ensue.

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7. Strength and Limitation of the Study

Strength of the study

The study participants were homogeneous between the two groups.

Limitation of the study

Lack of current literature done in our country with similar study design for comparison

8. Conclusion and recommendation

Conclusion

Patients with controlled hypertension were more likely to develop hypotension than normotensive patients under spinal anesthesia with 0.5% hyperbaric bupivacaine and there was a statistically significant difference in the incidence of hypotension occurrence between controlled hypertension and normotensive group. In response to hypotension vasopressor consumptions were higher in controlled hypertension than normotensive group. In addition to that the occurrence of bradycardia under spinal anesthesia were no statistical significance difference between the controlled hypertension and normotensive group.

In mean SBP between two groups was Statistically significant seen at 15min, 20min, 25min and 30min and there was also a statistical significant difference seen in mean MAP at 20^{th}, 25^{th} and 30^{th} min between the two groups under spinal anesthesia.

Recommendation

For anesthetist

Under spinal anesthesia Controlled hypertension patients was higher incidence hypotension than the Normotensive patients and in response to hypotension phenylephrine can be necessary to administer those who developed hypotension in patient's age 40 years and above undergo surgery below umbilicus. In addition to that atropine is necessarily administer to those who developed bradycardia.

For further researcher

We recommend additional randomized control trial should be done.

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Annexes:

I. Consent

Dear sir/madam

My name is_____. I am attending post graduate program in the field of anesthesia at Addis Ababa University. I am going to conduct my thesis on **comparing the hemodynamic response following spinal anesthesia between controlled hypertensive and normotensive patients undergoing surgery below the umbilicus** from October 12/ 2019-up to January 9 /2020 G.C. The information going to be obtained will help the government and other responsible bodies to reduce the incidence general anesthesia induced complication in patients with controlled hypertensive and normotensive patients which aimed to reduce air way manipulation such as difficult intubation, risk of aspiration and catecholamine stimulation will disturb to the hemodynamic status of the patient.

As a chance you were included in the study. So, we kindly request your involvement in the study and honest response to achieve the objective of the study. Your response will be completely confidential and you have full right either to refuse a single question or leave the study. However, your honest response to those questions will help us to asses and understand the effect. So we are requesting you to give honest response and keep participation.

Would you willing to participate in the study? Yes/No

Thanks for taking part in the study

For further question ask investigator

Tel. 0948443189

Email: leakeg321@gmail.com

Sign _____ date_____

ከቃለ መጠይቅ በፊት ፈቃደኝነ ት መጠየቂያ ቅጽ፡

ሰላምታ

ጤና ይስጥላኝ እኔ _____እባላለሁ፡ ፡ በአዲስ አበባ ዩንቨርስቲ አንስትዚያ ት/ቤት

የጥናት ቡድን አባል ነኝ፡ ፡ የ ጥናቱ ዋና አላማ በሆስፒታሉ ውስጥ ቀዶ ጥገና ለሚደረገላቸው ሰዎች የ ሚሰጠው የግማሽ ማደንዘዣ መድሀኒት የደም ግፊት ባላቸው እና በሌላቸው ሰዋች መካከል ሊያመጣ የሚችለውን የደም ግፊት መጠን ልዩነት መገምገም ነው፡ ፡ ይህንን በተመለከተ የተወሰኑ ጥያቄዎችን ልጠይቆት እፈልጋለሁ፡ ፡ መጠይቁ 2-5 ደቂቃ ብቻ የሚፈጅ ሲሆን ተሳትፎዎት ሙሉ በሙሉ በፅርሶ ፈቃደኝነት ላይ የተመሰረተ ነው፡ ፡

በዚህ ጥናት መሳተፎም ሆነ አለመሳተፎ በሆስፒታሉ ውስጥ በሚያገኝት አገልግሎት ላይ ምንም አይነት ለውጥ አያመጣም፡ ፡ የተመረጡትም በዚህ ሆስፒታል ቀዶ ጥገና ስለተደረገሎት ብቻ ነው፡ ፡ ቃለ መጠይቁን በማንኛውም ሰአት ማቋረጥ ወይም ጥያቄዎችን አለመመለስ ይችላሉ፡ ፡ ለጥያቄዎች የሚሰጧቸዉ መልሶች በሚስጥር የሚጠበቁ ሲሆን የርሶ ስም ወይንም እርሶን የሚለይ ማንኛውም መረጃ አይገለጽም፡ ፡ እንዲሁም የሚሰጥት ምላሽ ከርሶ ማንነት ጋር በማንኛውም መልኩ አይያያዝም፡ ፡

በጥናቱ ለመሳተፍ ፈቃደኛ ነዎት?

ፊርማ _____

II. Structured questionnaire form

Structured questionnaire form for comparison of hemodynamic response following spinal anesthesia between controlled hypertension and normotensive patients undergoing surgery below the umbilicus at black lion hospital, Addis Ababa, Ethiopia, 2020.

Part I: Socio- demographic characteristics			
S.no	**Variable category**	**Response**	**Remark**
01	Patient card number		
02	Age (years)		
03	Sex		
04	Weight (kg)		
05	Height (cm)		
06	BMI (kg/m2)		
07	Duration of hypertension (weeks/months/years)		
Part II: monitoring			
08	Monitored used intraoperative	Yes /No	
	1. Pulse oximetry		
	2. ECG		
	3. NIBP		
	4. Temperature		
	5. UOP		
	6. Capnography		
Part III: preoperative assessment			
09	ASA status		
10	Type of surgery		
11	premedication /antianxiety	• diazepam ____mg • midazolam _____mg • others _____mg	

12	Anti- hypertensive agent	• CC blockers • ACE inhibitors • Beta blockers • diuretics • morning nifidipine__mg • others _____	
Part IV: Intraoperative assessment			
13	Fluid Co-load (ml)		
14	Type of LA	• Name ____ • dose____ • Bari city____	
15	Gauge of spinal needle		
16	Vertebral interspace drug Administered	• L2-L3 • L3-L4 • L4-L5	
17	Time of local anesthetic administration in the sub arachnoid space (second/min)		
18	Peak level of sensory block	• T10 • T8 • T6 • T4	
19	Method of sensory block evaluate	• Cold water • Pinprick • Others	
20	Total Blood loss (ml)		
21	Total fluid used intraoperative (ml)		
22	Operation duration (min)		
Part V: Rescue medication administer			
23	Vasopressor	• Adrenaline _____mg	

		• Phenylephrine____mg • Nor adrenaline _____mg • Others_____	
24	Anticholinergic medication	• Atropine _____mg • Glycopyrolate_____mg • Scopolamine _____mg	

Part VI: Intraoperative vital signs

	Time	SBP		DBP		MAP		HR	
	Before performing spinal anesthesia (at operation table)	1st min	2nd min	1st min	2nd min	1st min	2nd min	1st min	2nd min
25	Average vital sign (base line)								
26	Immediate after S/A within one minute								
27	3 minute after S/A								
28	5 minute after S/A								
29	10 minute after S/A								
30	15 minute after S/A								
31	20minute after S/A								
32	25 minute after S/A								
33	30 minute after S/A								
34	35 minute after S/A								
35	40 minute after S/A								
36	45 minute after S/A								
37	50 minute after S/A								
38	55 minute after S/A								
39	60 minute after S/A								

Name of data collector :_____ sig _____

Date: _____