ADDIS ABABA UNIVERSITY COLLEGE OF HEALTH SCIENCE,

SCHOOL OF MEDICINE, DEPARTMENT OF ANESTHESIA

COMPARING EFFECT OF LATERAL VERSUS SITTING POSITION ON HEMODYNAMICS AND ONSET OF SENSORY BLOCK DURING INDUCTION TIME OF SPINAL ANESTHESIA IN PATIENTS UNDERGOING ELECTIVE CESAREAN SECTION, AT GHANDI MEMORIAL HOSPITAL ADDIS ABABA; ETHIOPIA: A PROSPECTIVE COHORT STUDY,2022/2023.

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RESEARCH THESIS TO BE SUBMITTED TO ADDIS ABABA UNIVERSITY DEPARTMENT OF ANESTHESIA AS PARTIAL FULFILLMENT OF REQUIREMENTS FOR THE MASTER OF SCIENCE IN ADVANCED CLINICAL ANESTHESIA.

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Full title of the research project	Comparing effect of lateral vs sitting position on maternal hemodynamics and onset of sensory block during induction time of spinal anesthesia for parturients undergoing elective cesarean delivery at Ghandi Memorial Hospital, Addis Ababa, Ethiopia 2022/2023.
Duration of project	From December 30-2022- April 30-2023GC
Study Area	Addis Ababa, at Ghandi Memorial Hospital
Total Cost of the project	25,000 Ethiopian birr
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CERTIFICATION

I am certify that the research entitled, Comparing effect of lateral vs sitting position on maternal hemodynamics and onset of sensory block during induction time of spinal anesthesia for parturients undergoing elective cesarean delivery; a prospective cohort study is my original work. Any literature and/or data cited in this article is listed in the reference section and for those who assist me during this study has been given an acknowledgement.

Author

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Approval of the board of examiners

1. Advisor

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3. External Examiner

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Abstract

Background: Spinal anesthesia is the preferred anesthetic technique for cesarean sections. It can be given in a lateral or sitting position. But maternal positioning affects hemodynamics and the spread of local anesthetic drugs that also affect the onset of sensory block. Post-spinal hypotension is the major problem that occurs after spinal anesthesia. It is defined as a decrease in systolic blood pressure greater than 20% of the baseline measurement. Even though precautionary measures have been taken to alleviate post-spinal hypotension, it still occurs at a rate of 30–90% after spinal anesthesia, and it needs research to indicate at what position it will be pronounced.

Objective: The main objective of this study was to compare the effect of sitting versus lateral position on hemodynamics and the onset of sensory block during the induction time of spinal anesthesia in patients undergoing cesarean section at Gandhi Memorial Hospital in Addis Ababa, Ethiopia, from December 30, 2022, to April 30, 2023.

Methods: A prospective cohort study was applied to 170 parturients who had undergone elective cesarean delivery under spinal anesthesia. Data was analyzed using SPSS version 27, after checking the normality of the data distribution. An independent t-test was used to analyze parametric data, and a Mann-Whitney u-test was used for the analysis of non-parametric data. A chi-square test was employed to compare categorical variables. A statistical significance is determined when $P < 0.05$.

Result: There was no statistically significant difference between the two groups in terms of sociodemographic data ($P > 0.05$). The incidence of hypotension in the lateral and sitting groups was 25% and 75%, respectively ($P = 0.036$). The lowest recorded median systolic blood pressure was 95 mm Hg in the lateral group and 87 mm Hg in the sitting group. The onset of sensory block was also faster in the lateral position than the sitting position ($P < 0.05$).

Conclusion and Recommendation: The changes in maternal hemodynamics were better maintained in lateral position than sitting position, and adequate sensory level for cesarean section is attained quicker in lateral position as compared to sitting position in patients undergoing spinal anesthesia for cesarean section. We recommend using the lateral position as the sole induction position during spinal anesthesia.

Acknowledgment

At the first level, I would like to thank Almighty God, my provider. Next my special thanks go to my advisors Mrs. Lidya Haddis and Mr. Fissiha Fente for their inspiring mentorship and enormous contributions during the entire period of writing this research proposal.

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List of Abbreviation

ASA - AMERICAN SOCIETY OF ANESTHESIOLOGIST

AKI: ACUTE KIDNEY INJURY

BMI: BODYMASS INDEX

CD - CESAREAN DELIVERY

CS: CESAREAN SECTION

CI: CONFIDENCE INTERVAL

CPD: CEPHALOPELVIC DYSPROPORTION

DBP: DIASTOLIC BLOOD PREASURE

ETB: ETHIOPIAN BIRR

G.C: GORGERIAN CALANDER

LLDP: LEFT LATERAL DICUBITUS POSITION

LP: LATERAL POSITION

MAP: MEAN ARTERIAL PREASURE

PR: PULSE RATE

PIH: PREGENCY INDUCED HYPERTENSION

PSH: POST SPINAL HYPOTENSION

RLDP: RIGHT LATERAL DICUBITUS POSITION

SBP: SYSTOLIC BLOOD PREASSURE

SD: STANDARD DEVATION

SA: SPINAL ANESTHESIA

SP: SITTING POSITION

SPSS: STASTISTICAL PACKAGE FOR SOCIAL SCIENCE

ZMH: ZEWDETU MEMORIAL HOSPITAL

Chapter one: Introduction

1.1 Backgrounds

Hypotension after spinal anesthesia, also called post-spinal hypotension, is defined as a reduction of systolic blood pressure by more than 20% from the baseline measurement after initiating spinal anesthesia. (1) Cesarean deliveries are the most common obstetric procedure worldwide, occurring at a rate of 8–36% in public hospitals and 10–80% in private hospitals, with 18.3% in Ethiopia, and specifically in Addis Ababa, where the rate is highest, at around 21.4%. It is performed when a vaginal delivery would endanger the mother or the child. (2)

Cesarean delivery can be performed with general or spinal anesthesia. (3) But now, spinal anesthesia is arguably the most common method of cesarean section. In the United States, approximately 95% of procedures are performed under regional anesthesia, like spinal, epidural, or combined spinal-epidural anesthesia. (2,3) Spinal anesthesia is the dominant one for cesarean section, which is done by the injection of a local anesthetic into the cerebrospinal fluid that surrounds the spinal cord and nerve roots and is used to perform procedures below the umbilicus. It is widely used during cesarean delivery in particular due to its proven success, increased patient satisfaction, simpler technique, rapid, profound, and symmetrical high-quality sensory and motor blocks with a low failure rate, and low drug dosage. (4)

Spinal anesthesia is also used to avoid the risks of general anesthesia, provide better postoperative pain relief, early return of bowel function, early ambulation, which is used to reduce the risk of deep venous thrombosis, and keep the woman awake to see her baby after delivery. (3, 5) As a result of these advantages, it is preferred by the majority of anesthesia providers and is currently the most commonly used method of cesarean section. (5)

Spinal anesthesia can be administered in either a sitting or lateral position, each with its own set of benefits and drawbacks. It can be easily performed in a sitting position due to the clear landmarks to appreciate the interspinous space for needle insertion, and can be performed with the two legs straight on the operating table or with the two legs on a stool beside the operating table. (6)

However, maintaining a sitting position is difficult for some patients, such as those who have taken sedative drugs like diazepam or magnesium sulfate, emergency patients who are in active labor, multiple gestations, umbilical cord prolapse, and anxious patients. In these cases, a lateral position with a pillow supporting the head and the operating table horizontal for spinal injection is preferable. (7)

Because of physiologic changes during pregnancy, spinal anesthesia causes significant maternal hemodynamic instability, like post-spinal hypotension (PSH), which is due to intracranial diffusion of local anesthetics in the subarachnoid space up to the T4-T1 level, reduced systemic vascular resistance as a result of sympathetic blockage, and aortocaval compression by the gravid uterus. PSH is the commonest hemodynamic instability after spinal anesthesia in obstetric patients, which causes hypoperfusion of the uterus and placenta, nausea, vomiting, shivering, and shortness of breath. If left untreated for a prolonged time, it causes hypoperfusion of vital organs and leads to injuries like AKI and ischemic stroke. However, the incidence and severity of hypotension, as well as the speed of onset of sensory block, are affected by maternal position by influencing the spread of local anesthetic solution in cerebrospinal fluid following intrathecal injection. (7, 8)

Studies of spinal anesthesia administration in different maternal positions have shown variable results on hemodynamic parameters. (9)

1.2 Statement of problem

In obstetric patients, spinal anesthesia can be administered in a sitting or lateral position based on the experience of the anesthesia provider and patient cooperation. But whatever the position used for induction of spinal anesthesia, it has an impact on maternal hemodynamics and the onset of sensory block. The major hemodynamic effect after delivering spinal anesthesia in the obstetric population is post-spinal hypotension, regardless of the induction position. (2)

The incidence of post spinal hypotension is reported by different authors. (3) A study in Ethiopia discovered 25–55.9% of spinal anesthesia-induced hypotension with increased severity in the supine position. (3), With a rate of 60.0% in Spain, 40.4% in Rwanda, 33% in Brazil, and 28.3% in Germany. (9)

Maternal position during the induction of spinal anesthesia also has an impact on the spread of local anesthetic solution within the cerebrospinal fluid. (4) This may influence the incidence and severity of hypotension and the speed of sensory block onset. Late onset of sensory block, which is affected by maternal position used for induction of spinal anesthesia, is another major problem, especially during urgent cesarean delivery, which needs immediate action for parturients who came with a diagnosis of non-reassuring fetal heartbeat, cord prolapse, and fetal distress.

During this time, rapid spinal anesthesia with a fast onset of sensory block is needed unless maternal and fetal lives are in danger. Related to this, some authors reported that the sitting position has a late onset of sensory block, but in other studies, it is a controversial issue whether the lateral or sitting position is optimal for the induction of routine neuraxial anesthesia for CS delivery. (7)

To reduce the occurrence and severity of post-spinal hypotension, different preventive measures have been proposed, like preloading, Coloading, shifting the uterus to the left, elevating the lower extremity, using low-dose local anesthetics, using adjuvants, and using vasopressors. (9)

Even though these measures are taken, numerous studies have found that post-spinal hypotension is the major problem worldwide, affecting 30–90% of patients despite taking precautionary measures. (4, 10) These factors, however, can be influenced by patient positioning during and immediately following the intrathecal injection. (11)

If left untreated, post-spinal hypotensive episodes have major risks to the mother, like loss of consciousness, aspiration,ischemia, nausea and vomiting, shivering, and shortness of breath, and to the fetus, hypoxia, acidosis, and neurological damage due to oxygen deprivation and brain injury, which leads to even death when prolonged. (9,11) It also has a major impact on patient experience and outcomes like increased hemodynamic disturbances, decreased satisfaction, increased time to stay at the hospital, increased adverse effects on maternal outcomes, and decreased quality of life (12).

1.3 Justification of the study

The prevention and alleviation of post-spinal hypotension are core responsibilities for anesthesia professionals. To assure this responsibility, indicating the effect of position on maternal hemodynamics and on the onset of sensory block after induction of spinal anesthesia via research may alarm them to give emphasis on using a position with less hemodynamic disturbance and better sensory block onset at the time of induction of spinal anesthesia.

Different studies have been conducted to compare and identify the position effect on hemodynamics and the onset of sensory block, but there are controversies in between them. Some authors reported that lateral position has less effect on maternal hemodynamics with a relatively fast onset of sensory block, while others reported that sitting position has less effect on maternal hemodynamics, and a few others showed that maternal position during induction of spinal anesthesia has no effect on hemodynamics or the onset of sensory block.

The presence of controversies between researchers makes it difficult to reach a general conclusion to establish the best position. So that we are not sure which position has less effect on maternal hemodynamics with a fast onset of sensory block. In addition to this, almost all of the studies have been conducted in developed countries. Research shows that sociodemographic characteristics and genetic differences can also affect blood pressure. So, post-spinal hypotension is a major problem that needs a quick intervention in our setup.

In our country as far as our knowledge and searching ability, The topic is not investigated yet. Therefore, this study was planned to determine the induction position with less hemodynamic effect and a fast onset of sensory block by evaluating hemodynamic parameters. So that, this study will be helpful primarily for clinical practice on planning to minimize post-spinal hemodynamic instability, for researchers as a source of information and a sole input to the literature, for educational purposes as a source of material for evidence-based teaching and learning processes, and for the community and parturients.

Chapter two: Literature review

Worldwide, cesarean sections for delivery of the fetus are now a dramatically increasing surgical procedure, arguably under spinal anesthesia, either in a sitting or lateral position, when a life-threatening condition occurs and in order to prevent complications for the mother or fetus. (15) Different studies have been conducted comparing the effects of spinal anesthesia administration in sitting and lateral positions with variable hemodynamic parameters and variable results on the onset of sensory blockade. (5)

B.I. Obasuyi et al. (2013) in Nigeria conducted a comparative study on 100 parturients and found that hypotension occurred less frequently in the lateral position as compared with the sitting position. The mean arterial blood pressure was greater in the lateral group, but there was no difference in terms of the lowest recorded systolic blood pressure in the lateral group (99.2 ± 8.9 mm Hg) compared with the sitting group (95.4 ± 12.3 mm Hg, P = 0.081). The lowest recorded mean arterial blood pressure was in the lateral group compared to the sitting group (72.9 ± 11.2 mm Hg vs. 68.2 ± 9.6 mm Hg; P = 0.025, respectively). The incidence of hypotension was lower in group L (17/50, 34%) than in group S (28/50, 56%; P = 0.027). And the onset of hypotension was similar among groups. (14)

A randomized clinical study conducted in Egypt by Simin A. et al. (2018 on 76 pregnant women showed that the lateral position is associated with greater hemodynamic stability, less vasoconstrictor use, fewer side effects, and better neonatal status (p = 0.016) when compared with the sitting position. And the incidence of hypotension was recorded at 63.15% of all patients. This indicates that despite the methods of prevention, complete prevention of hypotension during CS is not possible. Generally, the sympathetic blockade usually results in hypotension, whether the patient is in the sitting or lateral position. (12)

On the contrary, another comparative study conducted in Egypt in 2019 by Shamlool S. et al. on 60 patients reported that satisfactory sensory and motor blockade were successfully achieved in both sitting and lateral positions without significant differences in the hemodynamic changes (P = 0.67) or motor blockade (P =0.22).

With superiority of faster onset of sensory blockade in lateral position (P = 0.002), while there was no statistically significant difference between both groups regarding level of sensory block (P = 0.073). (9)

In 2017, Charge ND. et al. conducted a randomized comparative study on 120 parturients and reported that induction position didn't affect maternal hemodynamics and that there were no statistically significant differences observed between the two study groups in terms of mean heart rate, systolic, and diastolic blood pressure of patients during the entire observation period after induction of spinal anesthesia. There was no statistically significant difference in the sensory and motor levels achieved. However, the lateral position appears to be more comfortable than the sitting position (P <0.001). But the onset of spinal anesthesia was faster in the lateral group than in the sitting group due to the administration of hyperbaric bupivacaine. (16)

In India, Dr Neha Aeron and Dr Mahesh Vakamudi conducted a randomized comparative study in 2020 on 120 parturients and found that lateral position had a faster onset of sensory block and the first episode of hypotension was also faster as compared to sitting position (p = 0.00). The number of patients experiencing hypotension, the number of hypotensive episodes, and the total ephedrine requirement were significantly higher in the lateral position (p<0.05).(5)

Arshed M. et al. conducted a comparative study in Pakistan on 126 parturients in 2021 and reported that hypotension was observed more in the sitting position (p-value 0.012). (17)

In 2021, a comparative study conducted on 106 parturients by Nahid Manouchehrian et al. in Iran reported that, when spinal anesthesia is delivered in a lateral position, it has a fast onset of sensory and motor block, reduced ephedrine consumption, and increased maternal satisfaction (P < 0.05). The frequency of hypotension was 57.7% and 24.5% in sitting and lateral positions, respectively (P = 0.001). (2)

In 2022 in India comparative study was done on 100 patients and reported that patients in both groups were comparable with respect to age, height, weight, and BMI. The onset of sensory block to reach the T5 dermatome was less in the lateral group (P 0.001).

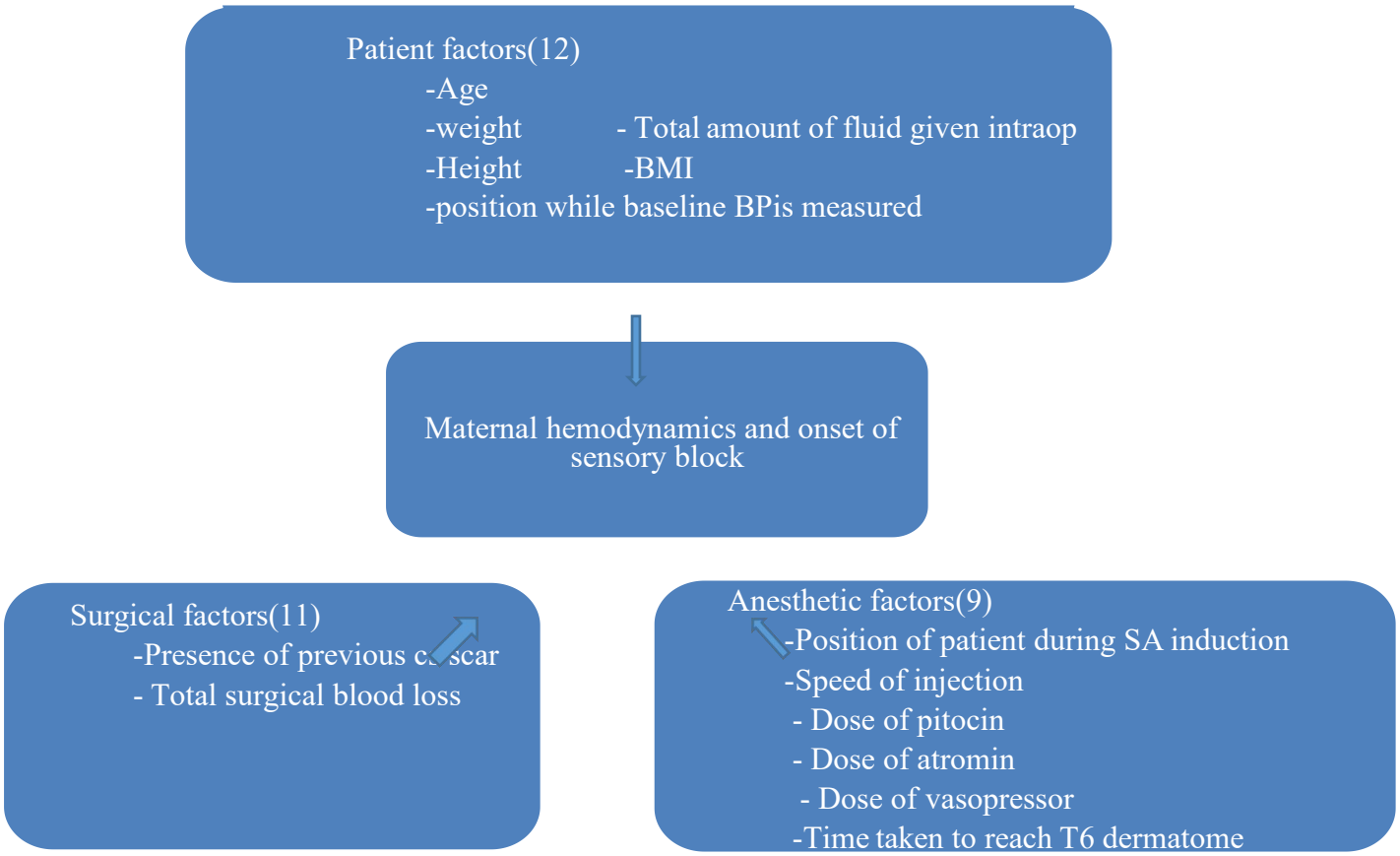
But mean arterial blood pressure was lower in the lateral group, and phenylephrine requirement was also higher in the lateral group (P = 0.047). (18)

In Spain, a randomized clinical trial conducted in 2015 by Navarra CH De et al. on 195 parturients reported that induction position has no effect on maternal hemodynamics, the incidence of arterial hypotension, or the requirement of phenylephrine and ephedrine. The incidence of hypotension was 60.0%.

There were no differences in the number of patients with hypotension (P = 0.09). There was no difference in ephedrine and phenylephrine requirements (P > 0.05). But induction of spinal anesthesia in the sitting position was easier technically and more comfortable for parturients. (9)

In general, the studies conducted on the comparison of lateral and sitting positions during induction of spinal anesthesia for parturients during cesarean delivery have shown different results in terms of hemodynamic parameters and onset of sensory block.

2.1 Conceptual frame work



2.2 Research hypothesis

Comparing the effect of sitting and lateral position on maternal hemodynamics and the onset of sensory block was hypothesized as follows:

HO1: There is no significant difference in terms of SBP, DBP, MAP, or PR among the groups.

HA1: There is a significant difference in terms of SBP, DBP, MAP, and PR among the groups.

HO2: There is no significant difference in terms of sensory onset block among the groups.

HA2: There is a significant difference in terms of sensory onset block among the groups.

Chapter Three: Objective

3.1 General Objectives

The aim of this study was to compare the effect of lateral versus sitting position on hemodynamics and the onset of sensory block during the induction time of spinal anesthesia in patients undergoing elective cesarean section at Gandhi Memorial Hospital from December 30-2022 to April 30-2023, Addis Ababa, Ethiopia.

3.2 Specific Objectives

- To compare the effect of position on maternal hemodynamics among groups during the induction time of spinal anesthesia in patients undergoing elective cesarean section at Gandhi Memorial Hospital from December 30-2022 to April 30-2023, Addis Ababa, Ethiopia.
- To compare the effect of position on the onset of sensory block among groups during the induction time of spinal anesthesia in patients undergoing elective cesarean section at Gandhi Memorial Hospital from December 30-2022 to April 30-2023, Addis Ababa, Ethiopia.

Chapter Four: Methodology

4.1 Study area and period

The study was done at Gandhi Memorial Hospital, which is located in Addis Ababa, the capital city of Ethiopia. The Hospital is one of the largest maternal and child care centers in the country and was founded in early 1958 by Mohandas Karamchand Gandhi. It has four operating rooms and 120 beds. Per day, an average of 8–10 cesarean deliveries are performed, and of these, more than half are elective cesarean procedures. The hospital serves as a teaching Hospital for the obstetrics and gynecology department in collaboration with the Addis Ababa University College of Health Sciences. The study was conducted from December 30, 2022, to April 30, 2023 G.C.

4.2 Study Design

A prospective observational cohort study was conducted from December 30, 2022, to April 30, 2023.

4.3 Populations

4.3.1 Source population

All parturients who underwent cesarean delivery at Ghandi Memorial Hospital, Addis Ababa, Ethiopia.

4.3.2 Study population

Elective arturients who had undergone cesarean sections under spinal anesthesia at Ghandi Memorial Hospital during the study period and those who fulfilled eligibility criteria

4.4 Eligibility criteria

4.4.1 Inclusion criteria

All ASA 2 pregnant parturients aged between 18 and 45 years who were candidates for elective cesarean section under spinal anesthesia either in a sitting or lateral position.

4.4.2 Exclusion criteria

Exclusion criteria

- Multiple pregnancies
- Hemodynamic instability, like severe hypotension due to antepartum hemorrhage
- Patient delivering under spinal anesthesia with added adjuvants
- Preexisting hypertension, or PIH
- Patient with extreme height (<140cm and >175cm)
- Parturient with cardiac and other end-organ disease
- Failure to achieve sensory block at the level of T6
- Used uterogenic agents other than oxytocin
- Dose of bupivacaine other than 12.5mg
- Level of intervertebral space other than L3/L4
- Volume of preload other than 500 ml

4.5 Sample size determination and sampling techniques

4.5.1 Sample size determination

The purpose of this study was to compare hemodynamic effect and onset of sensory block, so the sample size was calculated based on the mean value of mean arterial blood pressure at lateral and sitting positions (mean +/- SD was 72.9 +/- 11.2 and 68.2 +/- 9.6 for lateral and sitting positions, respectively) from existing literature (23) with 80% power and 95% confidence interval. By taking these, the sample size was estimated manually with an equal independent sample size formula for comparison of two means as follows:

$$n = (Z\alpha/2 + Z\beta)2\ \frac{(\delta 1)2+(\delta 2)2}{(\mu 1-\mu 2)2} = (1.96+0.84)2*\frac{(11.2)2+(9.6)2}{(72.9-68.2)2} = 170 \text{ with 10\% attrition}$$

Z/2 = 1.96 for a -error of 5% (95% CI), ZB = 80% (0.84) Power of study

Finally, a total of 170 parturients were included in two groups, including 85 subjects in the sitting position (group S) and 85 subjects in the lateral position (group L), with 10% contingency.

4.5.2 Sampling technique

By doing situational analysis in three months during the study period, 360 parturients who fulfilled inclusion criteria were estimated to undergo cesarean delivery under spinal anesthesia in both positions at Gandhi Memorial Hospital. By taking the prevalence of causes done within one year, an average prevalence of three months is taken to avoid seasonal variation. And from a sample size of n = 170, the sample interval was calculated as K^{th} =N/n = 360/170 = 2. Since systematic random sampling was approximately 2, the first sample was selected by lottery method from scheduled patients listed on the display board, and then data was collected in every third interval until the calculated sample size was achieved during the study period.

4.6 Study Variable

4.6.1 Dependent variables

- Hemodynamic changes
- Onset of sensory block

4.6.2 Independent variables

Maternal socio-demographic condition

- Age
- Height
- weight
- BMI

Preoperative obstetric characteristics and conditions

- Number of previous caesarean sections
- Maternal position while measuring baseline BP
- Total amount of fluid given intraoperatively
- Total surgical blood loss

Intraoperative anesthesia and surgery-related conditions

- Maternal positioning during the induction of SA
- Speed of injection
- Dose of Pitocin
- Dose of vasopressor
- Dose of atropine
- Time taken to reach T6 dermatome

4.7 Data collection procedure and tool

A pretested questionnaire was conducted at Zewditu Memorial Hospital with a 5% sample size. All patients on the schedule list who met the inclusion criteria were selected based on the skip interval, assessed, and given informed consent before coming to the operating room. When the patient came into the operation room and took 500 ml of preload volume with normal saline or lactated Ringer solution, they were observed in the study. Baseline vital signs were recorded in the supine position in the majority of patients while the operating table was tilted to the left side for prevention of aortocaval compression. Spinal anesthesia was given in the sitting and lateral positions by slowly injecting 0.5% of 12.5 mg of hyperbaric bupivacaine at L3–4 interspace. After SA was given, the patient was put in a supine position with pillows, and the level of block was assessed by cold sensation with alcohol and a pinprick.

Intraoperative hemodynamic parameters were filled by two trained BSC Anesthetists by using a time interval recording check list. And recorded before and after induction of spinal anesthesia in the supine position by a check list that was developed for this purpose. For the first 30 minutes after SA was given, it was recorded every 5 minutes; after that, it was recorded every 10 minutes up to the end of the procedure, and parturients were observed for the presence of nausea and vomiting from December 30, 2022, to April 30, 2023, at Ghandi Memorial Hospital, Addis Ababa, Ethiopia.

4.8 Data Quality Control and Assurance

Training was given to data collectors about the significance of the study and the tools used to record data. After that, data was collected using a structured questionnaire that was pretested on 5% of the sample size at Zewditu Hospital. The completeness, clarity, and accuracy of the collected data were always evaluated by the principal investigator and supervisor.

4.9 Data processing and analysis

When the data collection procedure was finished, the paper was checked for completeness and clarity, and then the data was entered and analyzed by SPSS version 27. The normality of the data distribution was checked with the Shapiro-Wilk test and Histogram. After that, parametric data within the group was analyzed by independent t tests and presented with mean and standard deviation, While non-parametric data was analyzed by Mann-Whitney U tests and presented with median and interquartile range. Categorical variables were analyzed by the chi square test and presented with numbers, frequencies, and percentages. A statistical significance was considered when the P-value was <0.05.

4.10 Ethical considerations

Ethical approval was obtained from the Addis Ababa University institutional review board before conducting the study, and an official letter was also submitted to the Addis Ababa health bureau. A letter for conducting the research at Gandhi Memorial Hospital was also obtained. Also, informed consent was obtained from each patient after clarifying the purpose of the study. Confidentiality was maintained, and patient identity was not recorded.

4.11 Dissemination and presentation plan

The result of the study is presented with figures and tables and will be disseminated to the AAU Department of Anesthesiology and the Addis Ababa Health Bureau. It will be presented at workshops and different seminars and finally submitted to a relevant scientific journal for publication.

4.12 Operational definitions

- **ASA:**American Society of Anesthesiologists, surgical risk stratification
- **Hemodynamic:** in this research, it's about arterial blood pressure**.**
- **Hypotension**: Hypotension was defined as a decrease in systolic blood pressure greater than 20% of the baseline. (2)
- **Onset of sensory block:** The duration of time between the injection of local anesthetics in the subarachnoid space and sensory level to reach the T6 dermatome.
- **Parturient**: A pregnant mother who is giving birth
- **Caesarean section** refers to a surgical procedure used to deliver a baby through an incision in the mother's abdomen and a second incision in the mother's uterus under anesthesia.
- **Spinal anesthesia** refers to a spinal block or subarachnoid block (SAB), a form of regional anesthesia involving the injection of a local anesthetic into the subarachnoid space, generally through a fine needle.
- **Sitting position:**where the patient sits on the operating table with both feet placed on a stool and both hips and knees maximally flexed.
- **Lateral position:** when the patient lies on her side with the pillow under the neck and her hips flexed.

Chapter Five: Result

5.1 Socio-demographic characteristics of the participants

All 170 parturients were involved in the study with 100% response rate. Statistical difference was not observed among the groups in terms of age, height, weight, BMI and presence of previous cesarean scar and majority of patients were at supine position while baseline vital sign was taken, as shown in **(Table 1).**

Table 1: Socio-Demographic Characteristics and preoperative condition Of Patients Undergoing Elective Cesarean Section under SA at Gandhi Memorial Hospital Addis Ababa, Ethiopia 2023.

Variable	L- Group (n = 85)	S- Group(n =85)	P- value
Age (year)	29.1±5.5*	28.25±4.37	0.241
Height (cm)	161.9± 6.05*	161.9±4.9	0.978
Weight (kg)	69.1± 6.5*	67.3±5.4	0.059
BMI (kg/m2)	23.7±1.56 *	24.0±1.92	0.342
Previous scar	21(42%)	29(58%)	0.194
Patients required vasopressor	2(22.2%)	7(77.8%)	0.087
Position of patient while BP is measured	supine position	159(93.5%)	<0.001
	Sitting position	11(6.5%)	

Hint:*=Mean (standard deviation); Value are presented as: Mean+SD: Independent t test, Number(%):chi-square test and p<0.05 is statistically significant.

Intraoperative fluid and vasopressor requirements

There is no significant difference in terms of total estimated blood loss, dose of oxytocin, or requirement of atropine among groups with a P-value >0.05, but for the total amount of fluid administered intraoperatively, there is a high fluid consumption among the sitting group (P < 0.05), as shown below in table 2. The mean adrenaline dose in patients under spinal anesthesia in the sitting position was higher (60.0±38.7 vs. 36.6±55.0 P = 0.05) than in the lateral group.

The incidence of hypotension and other complications

The overall incidence of hypotension was 9.4%. Out of this, in the sitting group, 12 (75%) and 4 (25%), were in lateral positions. The statistical analysis revealed a significant difference (p = 0.036). Patients in the sitting position while taking spinal anesthesia complained of nausea more than those taking spinal anesthesia at lateral position (32/74.4% vs. 11/25%; P<0.001, respectively). There was also a higher rate of vomiting among the sitting group than the lateral (23/88.5% vs 3/11.5%; P<0.001 respectively).

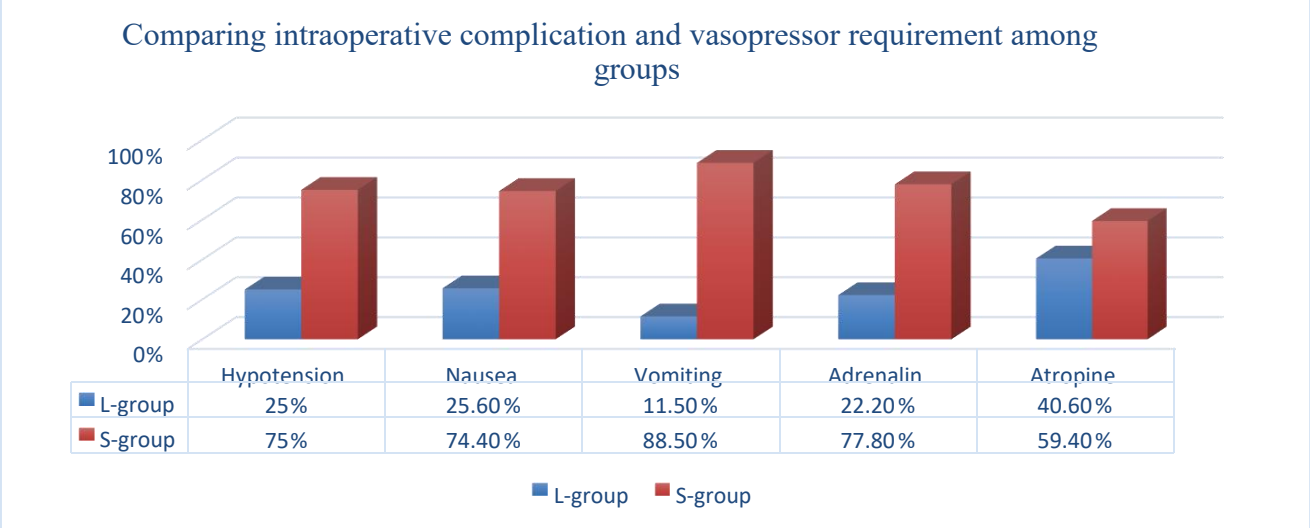


Figure 1: a column chart shows intraoperative complication rate and vasopressor requirement of patients underwent elective cesarean section under spinal anesthesia at Ghandi Memorial Hospital Addis Ababa, Ethiopia 2023.

Table 2: Intraoperative Conditions of Mothers Undergoing Cesarean Section Under Spinal Anesthesia At Ghandi Memorial Hospital Addis Ababa Ethiopia, 2023.

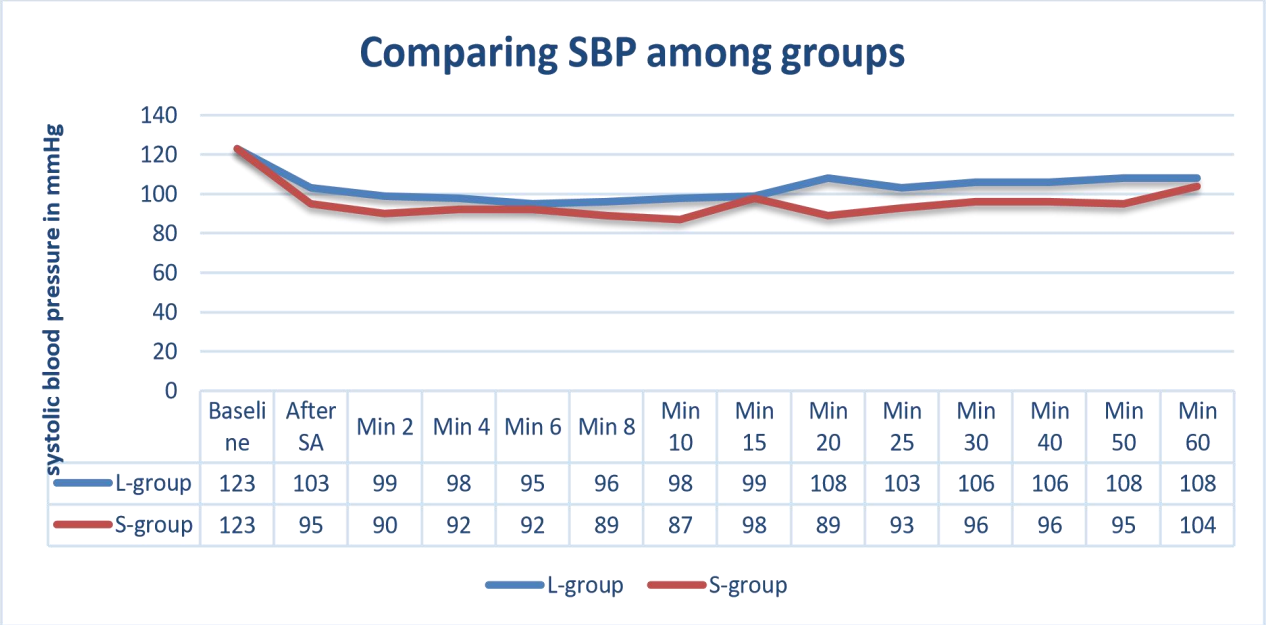
	L group (n=85)	S group (n=85)	P- value
Total intra-op fluid given	2000(200)**	2000(500)	0.002
Total surgically blood loss	650(90) **	650(50)**	0.063
Duration of surgery (min)	59.3±2.6 *	58.5±4.6	0.232
Dose of oxytocin (iu)	24.5±5*	24.4±5	0.99
Dose of atropine (mg)	0.54±0.08*	0.54±0.05	0.87
Dose of adrenalin (mic)	36.6±55.0*	60.0±38.7	0.05

Hint: *=Mean (standard deviation), **= Median (IQR) Value are presented as: Mean+/-SD for Independent t- test and Median (inter quartile range): for Mann Whitney u-test, and $p<0.05$ is statistically significant.

5.2 Comparisons of hemodynamic parameters among groups

Changes in the SBP (mm Hg)

There was no significant difference in baseline systolic blood pressure among groups with (P=0.461). While measurement of systolic blood pressure immediately after spinal anesthesia, at min 2, min 4, min 6, min 8, min 10, min 15, min 20, min 25, min 30, min 40 and min 50, showed a significant reduction in sitting group (P<0.05). The peak decreased systolic blood pressure was observed in the sitting group 87(15) vs 95(20) than lateral group respectively.



	Baseline	After SA	Min 2	Min 4	Min 6	Min 8	Min 10	Min 15	Min 20	Min 25	Min 30	Min 40	Min 50	Min 60
L-group	123	103	99	98	95	96	98	99	108	103	106	106	108	108
S-group	123	95	90	92	92	89	87	98	89	93	96	96	95	104

Figure 2: a line graph shows Systolic blood pressure (mmHg) measurement at different time intervals of patients underwent elective cesarean section under spinal anesthesia at Ghandi Memorial Hospital Addis Ababa, Ethiopia 2023.

Changes in the DBP (mm Hg)

There was no significant difference in baseline DBP, min 8, min 10, and min 25 among groups (P > 0.05), while measurement of DBP other than these minutes showed a significant reduction in the sitting group compared to the lateral group (P < 0.05). The first episode of reduction in DBP was persistent from immediately after SA to 8 min, and it was significant in sitting groups.

The lowest recorded DBP was 50 mmHg in sitting position and 52 mmHg in lateral group, which might also be due to position effect and sympathectomy.

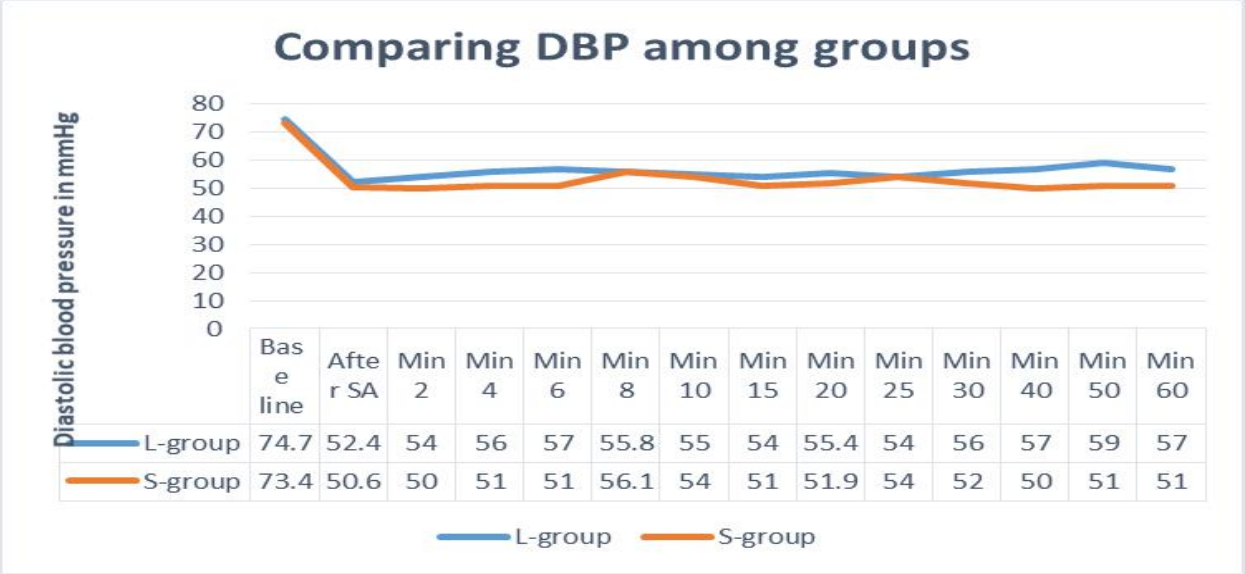


Figure 3: A Line Graph Shows Diastolic Blood Pressure (mmHg) at different time interval of patients undergoing elective cesarean section under spinal anesthesia at Ghandi Memorial Hospital Addis Ababa, Ethiopia 2023.

Changes in the MBP (mm Hg)

There was no significant change in base line MBP, at 8 minutes, 10 minutes, 25 minutes, and 60 minutes in both groups with $P > 0.05$, while measurement of MBP immediately after SA at 2 minutes, 4 min, 6 min, 15 min, 30 min, 40 min and 50 minutes showed a significant reduction in the sitting group than in the lateral group ($P< 0.05$), as shown in figure 4 below.

The first reduction of MAP was observed in the sitting group immediately after spinal anesthesia.

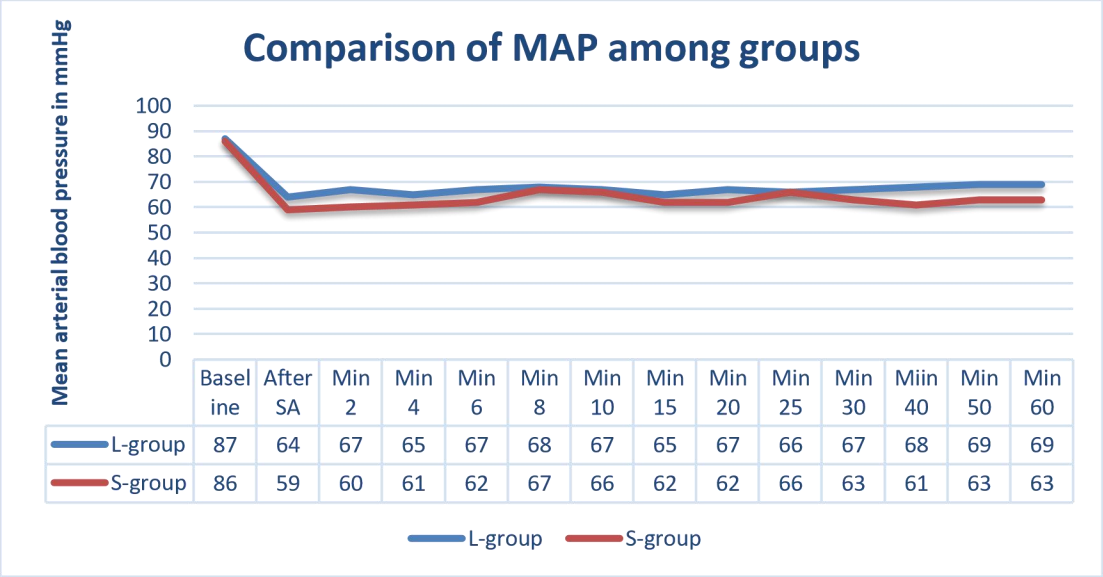


Figure 4: A Line graph Shows mean arterial blood pressure (mmHg) at different time interval of patients undergoing elective cesarean section under spinal anesthesia at Ghandi Memorial Hospital Addis Ababa, Ethiopia 2023.

Changes in the HR (beat/min) and SPO2(%)

There was no clinically significant change in terms of heart rate in either group throughout the procedure. while measurement of mean baseline SPO2 at minute 6 showed a significant change in patients in the lateral group than in those in the sitting group ($P < 0.05$). Its cause might be due to FRC reduction by pushing up abdominal contents in the supine position.

Table3. Comparison of SBP, DBP and MAP in S and L groups based on measurement time

	SBP (mm Hg)			DBP (mm Hg)			MAP (mm Hg)		
Time	**L-g**	**S- g**	**p-value**	**L-g**	**S- g**	**p-value**	**L-g**	**S- g**	**p-value**
Baseline	123(6)**	123(6)	0.461	74.7±6	73.4±7	0.241	87.5±4.2	86.8±6.5	0.397
After SA	103(8)	95(19)	<0.001	52.4±3.8	50.6±3.3	0.002	64.9±3.5	59.7±4.6	<0.001
Minute 2	99(4)	90(17)	<0.001	54(13)	50(11)	0.013	67(13)	60(14)	<0.001
Minute 4	98(16)	92(20)	0.015	56(9)	51(9)	<0.001	65(8)	61(12)	<0.001
Minute 6	95(20)	92(18)	0.034	57(12)	51(7)	<0.001	67(12)	62(10)	<0.001
Minute 8	96.1±10.4*	89.8±8.9	<0.001	55.8±8.5	56.1±8.4	0.822	68±8.9	67.9±8.8	0.993
Minute 10	98(18)	87(15)	<0.001	55(10)	54(10)	0.837	66.8±9	66.5±9.1	0.834
Minute 15	99(4)	98(9)	<0.001	54(7)	51(7)	0.006	65(9)	62(9)	0.011
Minute 20	108(8)**	89(16)	0.000	55.4±6.8	51.9±5.9	<0.001	67.4±7.4	62.9±6.9	<0.001
Minute 25	103(12)**	93(15)	<0.001	54(9)	54(9)	0.689	66.6±7.9	66.2±7.8	0.926
Minute 30	106.4±6.0*	96.8±10	<0.001	56(8)	52(5)	<0.001	67.8±6.7	63.9±5.5	<0.001
Minute 40	106.3±7.1*	96.6±8.7	<0.001	57(5)	50(7)	<0.001	68(9)	61(10)	<0.001
Minute 50	108.8±8.5*	95.2±8.7	<0.001	59(6)	52(5)	<0.001	69(7)	63(7)	<0.001
Minute 60	108.2±5.9	104.2±6.2	<0.001	57(7)	51(7)	<0.001	69(8)	63(10)	0.295

Hint: L- lateral group, S- sitting group, *= mean(standard deviation); ** Median (Inter quartile range), Value represented as: Independent t test: Mean(SD), Mann Whitney U test: Median(IQR), P<0.05 is significant.

Table4. Comparison of PR and SPO2 between groups based on measurement time

	PR (bpm)			SPO2 (%)		
Time	**L-g**	**S- g**	**p-value**	**L-g**	**S- g**	**p-value**
Baseline	83.3±4.6	83.3±3.9	0.742	97.6±1.4	96.9±1.4	<0.002
After SA	87.1±6.2	88.9±7.2	0.251	98.02±1.03	97.7±1.4	0.12
Minute 2	85(9)	79(9)	0.104	98(1)	98(2)	0.912
Minute 4	82(11)	80(9)	0.682	98(1)	98(1)	0.851
Minute 6	87(11)	82(9)	0.043	98(0)	98(1)	<0.001
Minute 8	83(9)	87(11)	0.593	98(1)	98(1)	0.707
Minute 10	87(11)	87(11)	0.526	98(1)	98(1)	1.00
Minute 15	84(9)	79(9)	0.313	98(2)	98(2)	0.453
Minute 20	80(10)	79(10	0.984	98(2)	98(1)	0.814
Minute 25	87(11)	87(11)	0.926	98(0)	98(0)	1.00
Minute 30	80(9)	83(9)	0.464	98(2)	98(0)	0.107
Minute 40	84(11)	80(9)	0.613	98(1)	98(2)	0.674
Minute 50	84(9)	81(9)	0.779	98(1)	98(2)	0.637
Minute 60	81(11)	79(8)	0.295	98(2)	98(2)	0.322

Hint: L- lateral group, S- sitting group, *= mean(standard deviation); ** Median (Inter quartile range), Value represented as: Independent t test: Mean(SD), Mann Whitney U test: Median(IQR), P<0.05 is statistically significant.

5.3 Comparison of spinal anesthesia characteristics among groups

The time to get T6 dermatome was faster in the lateral group 82(58.2%) within 2–5 minutes than 59(41.8%) sitting group with (P < 0.001). In terms of the number of attempts required to put the spinal needle in the subarachnoid space, it requires more attempts in the lateral position with a mean time of 1.5±0.5 minutes versus 1.1±0.3 minutes in the sitting position (P<0.001). For the total time taken to deliver spinal anesthesia, more time is also required in the lateral group with a mean time of (5.2±0.9 min than in the sitting position (3.7±0.8min) with a P<0.001. However, there was no significant difference between both groups in terms of speed of injection of bupivacaine (P>0.05) as shown in Table 5.

Table 5. Comparisons of Characteristics of spinal anesthesia among groups

		Lateral group	sitting group	P-value
Number of attempt to put spinal Needle in the subarachnoid space (Min)		1.5±0.5	1.1±0.3	<0.001
Speed of injection	**<10 sec**	1(100%)	0(%)	0.316
	10-15 sec	84(49.7%)	85(50.3%)	
Time taken for spinal procedure		5.2±0.9	3.7±0.8	<0.001
Time taken to reach T6 dermatome				
	0-2min	3(100%)	0(0%)	<0.001
	2-5min	82(58.2%)	59(41.8%)	
	>5min	0(0%)	26(100%)	

Hint: *= Mean(SD); **= Median(IQR); No(%)= number(percent), Values are represented as:- Mean (SD):Independent t test, Median(IQR): Mann Whitney U test, No(%): Chi square test and p<0.05 is considered statistically significant.

Chapter Six: Discussion

In this study, we observed that the lateral position is associated with greater hemodynamic stability, less vasoconstrictor use, fewer side effects, and a faster onset of sensory block when compared with the sitting position (P <0.05). Hypotension occurred less frequently in the lateral position compared with the sitting position. While the systolic blood pressure and diastolic blood pressure were decreased in the sitting group compared to the lateral group (P<0.05).

The induction position used for spinal block has affected blood pressure. In the present study, hypotension occurred more in the sitting group (12/75%) than in the lateral group (4/25%). This difference was significant (P=0.036). Also, the number of patients experiencing hypotension and the number of hypotensive episodes were observed to be higher in the sitting position as compared to the lateral position. As well, the duration of hypotension was greater in the sitting group, and the time to the first episode of hypotension was also significantly longer in the sitting position (p<0.001).

This finding was similar to that of B.I. Obasuyi et al. (2013), who conducted a comparative study on the effect of position on maternal hemodynamics and reported that Hypotension occurred less frequently in the lateral position compared with the sitting position. And the incidence of hypotension was lower in the lateral group (17/50, 34%) than the sitting group (28/50, 56%; P = 0.027). (14). Although this study's result is in line with a comparative study conducted by Abbas Moradi et al. in 2021 and Simin A. et al. in 2018, they reported that the frequency of hypotension was less in the lateral group than the sitting group (24.5% and 57.7%, respectively) (P = 0.001). (1) (12)

In the present study, the peak reduction of systolic blood pressure was observed in the sitting group immediately after the delivery of spinal anesthesia, at min 2, minute 8 and min 10. In lateral group at min 6 and min 8. This result is similar to a comparative study conducted by Manouchehrian et al in 2021, which reported that in minute 6 and minute 8 the mean systolic, diastolic and mean arterial blood pressure were significantly reduced in the sitting position than in the lateral position (P<0.05). (1)

Contrary to the present study, Dr. Neha Aeron et al**.** reported in their 2020 comparative study that the number of patients experiencing hypotension, the number of hypotensive episodes, and the total number of vasopressor bolus requirements were significantly higher in the lateral position as compared to the sitting position following induction of spinal anesthesia ($p<0.05$). (5)

In the present study, we observed that the time required for the onset of sensory blockade up to T6 was faster in the lateral group within 2–5 minutes (82/58.2%) than in the sitting group (59/41.8%) and was statistically significant with a $P < 0.001$. which corroborate the study of Dr Mahesh Vakamudi et al in 2020 and Nutan Dileeprao Kharge et al. in 2017 conducted a comparative study on the effect of position on the onset of sensory block and hemodynamics and reported that adequate sensory level for Caesarean section is attained quicker in lateral position as compared to sitting position within 2–5 minutes after injection of bupivacaine ($P<0.05$). (14)(16)

Although Nahid Manouchehrian et al in 2021 and Shamlool S. et al in 2019 reported similar results, when spinal anesthesia is given in the lateral position, it achieves a faster onset of sensory block as compared to the sitting position, with a statistical significance of ($P < 0.05$). (14) (2) Its reason could be related to, both cephalic and caudal spreading of drugs when given in lateral position .

In the present study, no significant difference was observed in terms of heart rate among groups. which is in collaboration with the findings of Nutan Dileeprao Kharge et al in 2017. (16) However, a study in Iran by Atashkhoeit Simin et al (2018) showed that bradycardia occurred in 8 (21.1%) of patients on sitting position which required treatment with atropine, while none of the patients in the lateral group had bradycardia.(12)

In this study, patients in the sitting group required adrenaline to treat hypotension (7/77.8% vs 2/22.2% P=0.087) than lateral group. In line to this study Atashkhoei Simin et al on 2018 conducted a comparative study and reported that patients in sitting group required vasopressor (29/76.3% vs 14/36.2% P=0.012) than lateral group.(12) This could be due to gravity dependent peripheral pooling and slower recovery from sympathectomy induced venous pooling in the lower extremity.

In this study, in terms of maternal side effects, nausea and vomiting were observed more in the sitting group (32/74.4%) than 11/25.6% in lateral group with (P<0.001). 23/88.5% of patients in sitting group has vomiting than 3/11.5% of patients in lateral group with statistical significance of (P<0.001). But this result was in contrary with Atashkhoei Simin et al on 2018 reported that, there was no significant difference in the incidence of maternal side effects like nausea and vomiting between lateral and sitting groups.(4) It could be related to using of metoclopromide as a prophylactic measure.

Chapter: Seven

7.1 Limitation of study

- Fetal outcome and maternal satisfaction were not considered in this study.
- Not including emergency cesarean section.
- Absence of previous cohort study in Ethiopia for comparison of the result of the present study.

7.2 Strength of study

The sociodemographic and preoperative factors were made comparable for avoiding its effect on outcome variable, so that the observed difference is may be due to effect of position during induction of spinal anesthesia. And we use a relatively large sample size compared to the other studies, which may increase the accuracy of the study.

7.3 Conclusion

In the present study, inducing spinal anesthesia at the lateral position has less effect on maternal hemodynamics, a faster onset of sensory block, and fewer maternal side effects like nausea and vomiting. But in terms of the number of attempts required and the total time required for the spinal procedure, it was higher in the lateral position than the sitting position.

7.4 Recommendation

We recommend anesthesia providers to use lateral position during induction of spinal anesthesia to maintain hemodynamic stability and decrease side effects followed by delivering spinal anesthesia in sitting position.

Researcher

- For future researcher we recommended to include fetal outcome and maternal satisfaction on their study.
- To include emergency cesarean section on their study population.

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Annex

Annex I: Information sheet to get permission for the research

Introduction

This information sheet is prepared to explain the research project that you are asked to join by a group research investigators. The research team includes Msc students, two senior advisors from AAU and two data collector from Gandhi Memorial Hospital.

Name of Principal investigator: -Nuru Yimam

Advisor's name: -Ms.:-Lydia Hadis

Mr.:- Fisiha Fente

Name of sponsor: -AAU

Name of organization: -AAU, Health science college, anesthesia department

This information sheet is prepared by the above-mentioned investigator.

Risk

There is no any risk or harm that you will face by participating in this research. Any personal information recorded will not be copied and transferred to other bodies. No need of writing participants' name. Every piece of information will be kept confidentially.

Benefits

There is no incentive or payment to be gained by taking part in this project. The information collected from this research project will be kept confidential and only accessed by the researcher and research assistant only. This research project will be reviewed and approved by ethical committee of the department.

Annex II: English Version Oral Consent

Dear participant:

My name is Nuru Yimam, I have been attending a postgraduate program in the field of anesthesia at Addis Ababa University. I am doing a research to compare effect of sitting versus lateral position on maternal hemodynamic during the time of spinal anesthesia induction. Data collection will be done during intraoperative period. To conduct our study, I would like to ask you some questions which may take about 10 minutes. As your participation is very important to the outcome of the study. Your participation is used to overcome the problem and improve effect of position after spinal anesthesia delivery. I kindly request you to give us your sincere and truthful answer. All the information that you and other patients going to provide us will remain confidential and you don't need to mention your name.

Are you willing to participate in the study, please? YES/NO (please encircle your response)

If your answer is no, you don't have to continue to the following questions. Thank you!

If your answer is yes, please continue your response to the following questions.

Thank you for taking part in the study!

Signature of the interviewer certifying that consent has been obtained verbally.

Signature _____ Date _____

For further question ask investigator Nuru Yimam

Tel: - +251922925832 E-mail:- nuruimam605@gmail.com

Annex III: **Amharic Version Oral Consent**

የተከበራችሁ የጥናት ተካፋዮች የዚህ ጥናት ዋና አላማ በቀዶ ጥገና የሚወልዱ እናቶች የሚወስዱትን ግማሽ ወይም ከወገብ በታች የሚሰጠውን አንስቴዢያ ኦፕሬሽን አልጋ ላይ ተቀምጠው ሲሰጥና በግራ ጎናቸው ተኝተው ሲሰጥ የሚያስከትለውን ተፅእኖ ለማወዳደርና የተሻለውን በመምረጥ እናቶች ላይ በአንስቴዢያው ምክንያት የሚፈጠረውን ችግር ለመቅረፍ ነው። በአጋጣሚ እርስዎ በዚህ ጥናት ላይ እንዲሳተፉ ተመርጠዋል። የዚህ ጥናት ጥቅም እርስዎ በሚሰጡት ምላሽ መሰረት መረጃወችን በማሟላት በሚገኘው ውጤት መሰረት መረጃዎችን በማጠናቀር ውጤቱ እየተሰራበት ካለው ጋር ለማገናዘብ እንዲቻል ነው፡ ለኛም ጥናቱ በትክክል አላማውን እንዲመታ የእርስዎን ድጋፍ እንጠይቃለን። የማንኛውም ግለሰብ ስም አይመዘገብም እንዲሁም ሃሳባቸው በይፋ እንዲወጣ አይደረግም። ሙሉ በሙሉ በሚስጥር የተጠበቀ ነው። በጥናቱ የመሳተፍም ያለመሳተፍም ሙሉ መብት አለዎት። ግልጽ የሆነ ምላሽ እና ከልብ የመነጨ ተሳትፎዎን እንዲሰጡን በአክብሮት ለመጠየቅ እንወዳለን።

-ለመሳተፍ ፈቃደኛ ነዎት? ሀ, አዎ ለ, አይደለሁም

-መልስዎ አዎ ከሆነ የመከተሉትን ጥያቄዎች ይመልሱልን።

-ለመሳተፍ ፈቃደኛ ስለሆኑ እናመሰግናለን።

-ለጥያቄ መልስ ለመስጠት እርስዎ የቃል ፈቃድ መስጠትዎ ን ለማረጋገጥ መረጃ ሰብሳቢ ባለሙያ ይፈርሙልን።

-የሰብሳቢው የማረጋገጫ ፊርማ:_____ ቀን :

_____

Annex IV: Questionnaire

Instruction: For each question, please circle the number of alternative (s) that fit the response and fill the black space provided or choice from the given alternatives

Position of patient----------

Part 1: Sociodemographic characteristic of mothers

1	Age	_____Year
2	Height	_____Cm
3	Weight	_____Kg
4	BMI	_____kg/m2

Part 2: Obstetric characteristics and Preoperative factors

5	Does the patient has previous cesarean section	1- yes 2- No
6	If yes, How many scar does the patient has (in number)?	-------
7	At which position (sitting or supine) baseline BP is measured?	----------position

Part 3: Measurement of Systolic, Diastolic, Mean Arterial Pressure, PR and SPO2

Measurement Time		SBP (mmHg)	DBP (mmHg)	MAP (mmHg)	Pulse Rate(BPM)	SPO2(%)
8	Before spinal Anesthesia					
9	Immediately after spinal anesthesia					
10	Minute 2					
11	Minute 4					
12	Minute 6					

13	Minute 8					
14	Minute 10					
15	Minute 15					
16	Minute 20					
17	Minute 25					
18	Minute 30					
19	Minute 40					
20	Minute 50					
21	Minute 60					

Part 4: **Intra operative anesthesia and surgery related associated factors**

22	Speed of injection	--------sec
23	Number of attempt required to put spinal needle in the subarachnoid space?	----------
24	Time taken to deliver spinal anesthesia?	----------minute
25	Time to get sensory block at the level of T6	--------minute
26	What is the dose of oxytocin?	--------international unit
27	Did you use vasopressor intra operatively?	1- Yes 2- No
28	If yes, what type of vasopressor is used?	1- Adrenaline 2- Ephedrine 3- Phenylephrine
29	Dose of vasopressor?	-------mg/mic
30	Did you use atropine?	1- yes 2- No

31	If yes, what is the dose of atropine?	---------mg
32	Dose of oxytocin	----------iu.
33	was there any episode of nausea after spinal anesthesia	1- yes 2- No
34	Was there any episode of vomiting	1 yes 2 No
35	Total amount of intra operative fluid given	-----ml
36	Total surgical blood loss	-----ml
37	Time from intrathecal injection to end of surgery	--------minute
38	Does the patient has hypotension? (a reduction of SBP by more than 20% from baseline measurement)	1- Yes 2- No