

**Addis Ababa University
College of Health Sciences
School of Medicine
Department of Anesthesia**



**INCIDENCE AND ASSOCIATED FACTORS FOR HYPOTENSION AFTER
SPINAL ANESTHESIA DURING CESAREAN SECTION AT GANDHI MEMORIAL
HOSPITAL ADDIS ABABA, ETHIOPIA, MAY 2019.**

By: Temesgen Mamo

Advisors

Luelayehu Akalu -Assistant Professor

Selam Jima (B.Sc. M.Sc)

**A THESIS SUBMITTED TO DEPARTMENT OF ANESTHESIA, COLLEGE OF
MEDICINE & HEALTH SCIENCES, ADDIS ABABA UNIVERSITY, IN PARTIAL
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ADDIS ABABA, ETHIOPIA

ADDIS ABABA UNIVERSITY
COLLEGE OF MEDICINE AND HEALTH SCIENCES
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By: TEMESGEN MAMO (BSC)

Address: Tel: +251-912-107804

E-mail: temesgen.mamo@gmail.com

Approved by the Examining Board

Head, Department of Anesthesia

Advisors

1. _____

2. _____

Examiner

Declaration

I, the undersigned, declare that this thesis is my original work in partial fulfillment of the requirements for the Master of Science degree in Anaesthesia. I understand that plagiarism will not be tolerated and all directly quoted material has been appropriately referenced

Name: _____

Signature: _____

Submitted to MSc Tutor, Department of Anesthesia Addis Ababa University.

Date of Submission: _____

This thesis work has been submitted for examination with my/our approval as Advisors and Tutors on the Master of Science degree in Anaesthesia

Name Signature

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Abbreviations/Acronyms

AOR	Adjusted Odds Ratio
ASA	American Society of Anesthesiology
BMI	Body Mass Index
CI	Confidence Interval
COR	Crude Odd Ratio
C/S	Cesarean Section
CSF	Cerebro spinal fluid
G	Gauge
LA	Local Anesthetic
GA	General Anesthesia
L	Lumbar
OR	Odds Ratio
OT	Operating theatre
SA	Spinal Anesthesia
SBP	Systolic Blood Pressure
SIH	Spinal induced hypotension
SPSS	Statistical Packages for Social Science

Abstract

Introduction: Spinal anesthesia is a type of regional anesthesia, has been practiced for obstetric anaesthesia since the beginning of the 20th century. so it is easy to perform and reliable as well avoids the depressant effects of anesthetic drugs and has a potential to provide excellent operating conditions for caesarean section. Hypotension is a usual consequence of sympathetic motor and sensory block caused by spinal anesthesia for cesarean section.

Objectives: The objective of the study is to determine the incidence and associated factors for hypotension after spinal anesthesia during cesarean section at Gandhi memorial hospital, Addis Ababa, Ethiopia.

Method: Institutional based cross sectional study was conducted on 422 clients using structured questionnaire until the end of the operation. The study was conducted on cesarean section under spinal anesthesia from January, to April 30, 2019 at Gandhi memorial Hospital, Addis Ababa, Ethiopia. Systematic random sampling technique was used for selecting the sample. Both bivariate and multivariate logistic regression analysis were done for associated factors. Level of statistical significance was declared at p-value less than 0.05.

Results: The incidence of hypotension among mothers who undergone cesarean section after spinal anesthesia was 64%. Neonate weight of 2.5-3.9kg AOR=3.440; 95% CI:(1.441-8.211) and greater than 4kg AOR=4.957; 95%CI: (1.563-15.722) showed increased association with hypotension. A baseline systolic blood pressure less than 120mmHg AOR= 5.527; 95%CI: (2.695-11.336), and in the range of 120-130mmHg AOR=3.583; 95%CI: (1.980-6.485) was associated with hypotension. Sensory block height >T6 AOR= 2.272; 95%CI: (1.362-3.788) and the time interval between spinal induction and skin incision > 6minutes AOR=1.758;95%CI: (1.022-3.024) are also associated with hypotension after spinal anesthesia.

Conclusion: The risk of hypotension is high in cesarean section after spinal anesthesia. The identified risk factors for spinal anesthesia induced hypotension are sensory height block, weight of the baby, time interval between spinal induction and skin incision, the baseline systolic blood pressure and experience of anesthetist.

Key words: hypotension, spinal anesthesia, cesarean section, Addis Ababa, Ethiopia

1. Introduction

1.1. Background

The practice of performing spinal anesthesia in Ethiopian hospitals are increasing and most of the mothers are happy with spinal type of anesthesia and agree to prefer spinal anesthesia for their future delivery and it is preferred by both mothers and health professionals because of its unique advantages.(1)

Spinal anesthesia is a type of regional anesthesia, has been practicing for obstetric anaesthesia since the beginning of the 20th century. Now a days regional anesthesia has become the most preferred anaesthetic technique for cesarean section, not only due to its simplicity and rapid onset along with maternal comfort and safety, but also because of the serious risks associated with general anesthesia.(2)

Spinal anesthetic block is most commonly preferred for cesarean section due to its simple technique, rapid onset, dense motor and sensory block.(3) In Ethiopia cesarean section delivery prevalence was 32.5% and those mothers who delivered by spinal anesthesia was 68.2% .(1)

Generally regarded as one of the most reliable types of regional anesthesia technique, Spinal anesthesia, requires a relatively easy needle insertion technique in which cerebrospinal fluid is a clear indication of successful needle placement in subarachnoid space and through which local anesthetics agents spread readily. (4)

Spinal anesthesia is commonly used for cesarean section delivery and having an advantages of decrease risk of local anesthetic toxicity and fast onset of local anesthetic effects, effective and the mother will be awake, interact with the neonate and remain comfortable, effective post-operative pain relief for mothers and which will avoid maternal morbidity and mortality associated general anesthesia. (5)

According to association of united kingdom of consultant obstetric anesthetists the definition of hypotension that needs anti-hypotensive measures is when the systolic blood pressure less than 100mmHg.(6)

The physiological mechanism of spinal induced hypotension (SIH) is related to the sympathectomy that results in a reduction of the tone of splanchnic vasculature and the lower limbs. This decrease in systemic vascular resistance leads to venous pooling and therefore results a reduction in venous return. The consequence reduction in preload, thus affects the cardiac output. These changes in preload may promote particular paradoxical reflexes that may worsen the condition and result in circulatory collapse.(7)

Hypotension is a usual consequence sympathetic motor block caused by spinal anesthesia for cesarean section results in maternal complications like nausea, vomiting, dyspnea frequently along with severe hypotension and adverse effects on fetus, including poor Apgar scores and umbilical acidosis has been related with severity and duration of hypotension. (8)

Hypotension commonly occurs in pregnant mothers who undergo cesarean section under spinal anesthesia, leading to maternal and neonatal complications such as nausea, vomiting and fetal acidosis even this may lead to cardiovascular collapse if not treated early.(3)

Hypotension is a common clinical problem faced by patients after spinal anesthesia and the severity can lead to both maternal and fetal complications like, nausea ,vomiting ,aspiration on mothers and fetal acidosis.(5)

In a study by Asim Shekahr et al. a grading system for hypotension was used. Moderate hypotension was regarded as a decrease in more than 20% from the baseline blood pressure and severe as more than 30% decrement from the baseline systolic blood pressure. (9)

Hypotension decreases cerebral perfusion, induces transient brainstem ischemia and stimulates vomiting center and may result in transient cerebral hypoxia due to severe hypotension.(10)

Hypotension is caused by temporary sympathectomy leading to decreased preload and reduced afterload(decreased systemic vascular resistance ,resulting in lower maternal mean arterial blood pressure and decreased uteroplacental perfusion.(11)

Now a day the use of GA has decreased dramatically because of a higher risk of anesthesia-related maternal morbidity and mortality as a result, spinal anesthesia (SA) is now the technique of choice for cesarean section(CS).(12)

The incidence of hypotension is higher in cesarean section due to cardiac changes of the parturient, compression of inferior vena cava by hypertrophic uterus and developing of collateral venous plexus circulation in the epidural space, leading to a decrease in the amount of cerebrospinal fluid (CSF) in the lumbosacral area and higher cephalad spread of local anesthetics. (13)

The normal physiological changes of full term pregnant women and dehydration can lead to the highest incidence of hypotension after spinal anesthesia.(14)

The most common definitions of hypotension after spinal anesthesia for caesarean section delivery is more than 20% reduction from base line systolic blood pressure, comparing it to initial values or absolute systolic blood pressure values less than 90 mmHg.(15)

The risk of hypotension is increased in those pregnant mothers due to the higher level of sensory block (T5) required for the cesarean section, physiologic changes of pregnancy and increased susceptibility to the effects of sympathectomy due to reduced sensitivity to the endogenous vasoconstrictors and increase synthesis of endothelium derived vasodilators.(16)

When speed of local anesthetic injection to subarachnoid space is slower it has a contribution for lower incidence of maternal hypotension.(17) The incidence was highest in cesarean section by means of any definition .(18)

1.2 Statement of the problem

Hypotension after spinal anesthesia is a common complication with an incidence ranging from 25-75% among general population in the world and, but a little higher in patients undergoing caesarean section. Usually, spinal induced hypotension can be significantly severe, which is more common in pregnant mothers, which can increase intra-operative and post-operative morbidity.(19,20)

In America ,retrospective study among 919 term parturient undergoing elective delivery under spinal anesthesia, 46.5% of those mothers have encountered a decrease in blood pressure more than 30% from the base line mean arterial blood pressure and 7.6% of pregnant mothers encountered a decrement of greater than 50% from base line mean arterial blood pressure.(21)

The South African saving mother's report of 2008 to 2010 revealed that 79% of anesthesia related deaths were because of spinal anesthesia. It is specifically stated that two thirds of the deaths were directly related spinal anesthesia induced hypotension.(22)

Prolonged and severe maternal hypotension may result in dizziness and decreased level of consciousness if not treated quickly.(10) The duration of hypotension might be more determinant than severity, transient greater than or equal to 30% reduction in blood pressure did not affect neonatal Apgar scores.(21)

Comprehensive report done by prof. J. Moodley, stated 2.5% of all maternal death was associated with maternal hypotension. Furthermore, hypotension has been related with maternal and fetal morbidity. (22).

Spinal block –induced sympatholytic leads to vasodilatation and hence, causes maternal hypotension which leads to a attenuation in systolic arterial blood pressure and can compromise uterine blood flow and fetal circulation which results in hypoxia and fetal acidosis. (23)

Hypotension for less than two minutes did not affect neonatal neurobehavioral outcomes whereas more than four minutes of maternal hypotension was associated with neonatal neurobehavioral outcomes changes at four up to seven days of life.(24)

1.3 Justification of the study

Despite many research in the past, hypotension after spinal anesthesia for cesarean delivery remains a common clinical problem that is associated with morbidity for both mother (nausea and vomiting) and fetus (fetal acidosis). The prevention and treatment of maternal hypotension associated with spinal anesthesia for cesarean section remains a problem. Protocols that aim to prevent hypotension during spinal anesthesia for C/S may result better outcomes than protocols of treatment after the hypotension occurred.

However, most of the study done in abroad showed that, there is a trend of using prophylactic measures to reduce the incidence of hypotension after induction of spinal anesthesia for caesarean sections. Due to drug constraints and expensiveness in our country it is not common to use prophylactic vasopressor to reduce incidence and severity of spinal induced hypotension. So to reduce hypotension and related maternal and fetal complication it is better to identify associated factors.

Spinal anesthesia is widely used for cesarean section in most of our set up. So hypotension is one the most frequent and common side effects of spinal anesthesia. Having knowledge on the risk factors for hypotension is mandatory which will increase the vigilance in those mothers most at risk of hypotension, enabling a timely therapeutic intervention and may guide clinical decision making.

The complications of spinal anesthesia which is hypotension on those patients and the cost of managing this complication is huge burden on the country's economy. Hence, it is highly recommended to conduct such research in our set up to see the incidence and associated factor for hypotension after spinal anesthesia during cesarean section. The findings of this study can be used to know the incidence of hypotension after spinal anesthesia in the study area.

2. Literature review

2.1 Incidence of spinal induced hypotension

Spinal anesthesia is a type of regional anesthesia where conduction block of nerve roots is achieved by administering a small volume of local anesthetic agent into the subarachnoid space through a lumbar puncture. It produces complete analgesia with profound muscle relaxation.(25) A Survey undertaken in Europe by Lirk et al. in 2012 showed the incidence of spinal induced hypotension at 42%.(26) In a Cross sectional study done in Germany with 503 mothers who underwent cesarean delivery under spinal anesthesia, the incidence of hypotension was 56.5%.(27)

Study done in Thailand, Chulalongkorn University Bangkok among seven hundred seventy two who underwent cesarean section by spinal anesthesia, the incidence of hypotension was found out to be 52.6% whereas, a study done in Iran which compared crystalloid, colloid and prophylactic ephedrine with lower extremities bandage showed the incidence of SIH as 54%,64%, and 36% respectively.(14,28)

According to research done in India with 502 mothers who underwent cesarean delivery under spinal anesthesia the incidence of hypotension vary with three category of hypotension mild, moderate, and severe were 20%,35% and 40%.(29) In a research undertaken at Siriraj Hospital, Mahidol University, Bangkok the incidence of hypotension after spinal anesthesia was 65.1%.(30)

A Study in Nigeria in 2010 by Adigun et.al, which compare the effects of phenylephrine and ephedrine the reported incidence of SIH was 24.2%.(31) In South Africa there was dramatic increase in cesarean section being performed is associated with high incidence of SIH. It contributes for spinal related deaths rate by 42%.(32)

Cross sectional study done in Ethiopia with pregnant mothers who underwent cesarean section by spinal anesthesia the incidence of hypotension is 36.6%.(1)

The incidence of hypotension varied by definition of hypotension and cut point. The incidence was 57.9% when hypotension was defined as reduction of systolic blood pressure by more than 20% of the baseline. This incidence reduced to 47.9% when two criteria were used (reduction to 20% of baseline value and systolic blood pressure lower than 100 mmHg).(18)

2.2. Associated factors for spinal induced hypotension

According to the research done in Addis Ababa in two hospitals the experience of anesthetist was identified as an associated factor for hypotension in which the occurrence of hypotension during cesarean section decreased as the experience of anesthetist increases (AOR;3.27(95%CI: 1.54-6.97)) (P<0.001)..(1)

The Patient's age of ≥ 35 years increased the incidence of hypotension in AOR 1.63 (95% CI 1.05,2.52), the same as BMI ≥ 35 had an AOR of 2.79 (95% CI 1.29,6.06) and sensory level $\geq T5$ had AOR of 1.56 (95% CI 1.12,2.18).(30)

According to study done in South Africa increased incidence of hypotension was observed in relation with advanced Maternal age >35 years (OR;1.05 (95%CI: 1.02 - 1.08)) Preoperative MAP <90mmHg (OR 0.97 (95%CI 0.95 - 0.98)) and Preoperative heart rate >90 beat per minute (OR 1.02 (95%CI 1.00 - 1.03)).(33)

Study done in Chulalongkorn University Bangkok, intraoperative estimated blood loss > 1000 mL showed strong association (OR 5.31), with hypotension while estimated blood loss 500-1000mL had OR 1.86. The maximum block height > T4 was associated with increased risk of hypotension (OR 1.94). Left uterine displacement was associated with increased risk of hypotension (OR 1.56).(14)

According to study done in Siriraj Hospital, Mahidol University, Bangkok 10700, Thailand Patient's height of less than 155 cm increased the incidence of hypotension in OR of 1.44 (95%CI 1.01, 2.06), the same as sensory level T5 or higher OR was 1.70 (95%CI 1.15,2.51).(34)

The base line of systolic blood pressure 120-130 mmHg strong association with decreasing risk for hypotension OR 1.96 (95%CI 1.23, 3.11) and base line systolic blood pressure < 120 mmHg increase incidence of hypotension OR 2.14(95% CI 1.53, 2.99).(34)

The research done by carpenter et al. the site of spinal block above or at L2-L3 interspace was strongly associated with hypotension (OR=1.8;95%CI:(1.3-2.5) (35)

According to research done in India BMI of 25–30 kg/m² was just associated with the development of moderate hypotension relative risk ratio (RR = 4.9, P = 0.02). Besides, baseline SBP <120 mmHg with RR of 6.5 (P = 0.01) and 4.8 (P = 0.001) was associated with the development of mild and moderate hypotension, respectively. Weight gain of 11–20 kg relative risk ratio (RR = 5, P = 0.003) and baseline HR >100 beats/min (RR = 5.1, P = 0.02) were associated with the development of severe hypotension.(29)

According research done in India amongst the factors in anesthesia-related multivariate

model, three were found to be statistically associated with hypotension. Fluid preloading ≥ 1000 ml (with RR = 0.25 [$P = 0.003$] and RR = 0.34 [$P = 0.04$] for mild and moderate hypotension, respectively) and adding 1 μg sufentanil to the injected local anesthetic compared to pure bupivacaine (with RR = 0.19 [$P = 0.02$] and RR = 0.15 [$P = 0.008$] for moderate and severe hypotension, respectively) were associated with decreased risk of hypotension. However, sensory block height higher than T4 was related to a higher incidence of hypotension (with RR = 5.07 [$P = 0.04$] and RR = 7.33 [$P = 0.01$] for moderate and severe hypotension, respectively).(29)

Amongst them, baseline SBP < 120 mmHg (RR = 6.53), history of hypotension (RR = 6.98) and gravidity ≥ 4 (RR = 6.84) were the strongest predictors for mild, moderate and severe hypotension, respectively.(29)

Amongst anaesthesia-related predictors, sensory block height $\geq T 4$ was the strongest predictor associated risk factor (RR = 7.33)(29)

The weight of the newborn was identified as associated risk factor for developing hypotension (RR 2.12, 95% CI 1.52-3.54) when it is higher than 3900 g.(36)

2.3 Conceptual framework

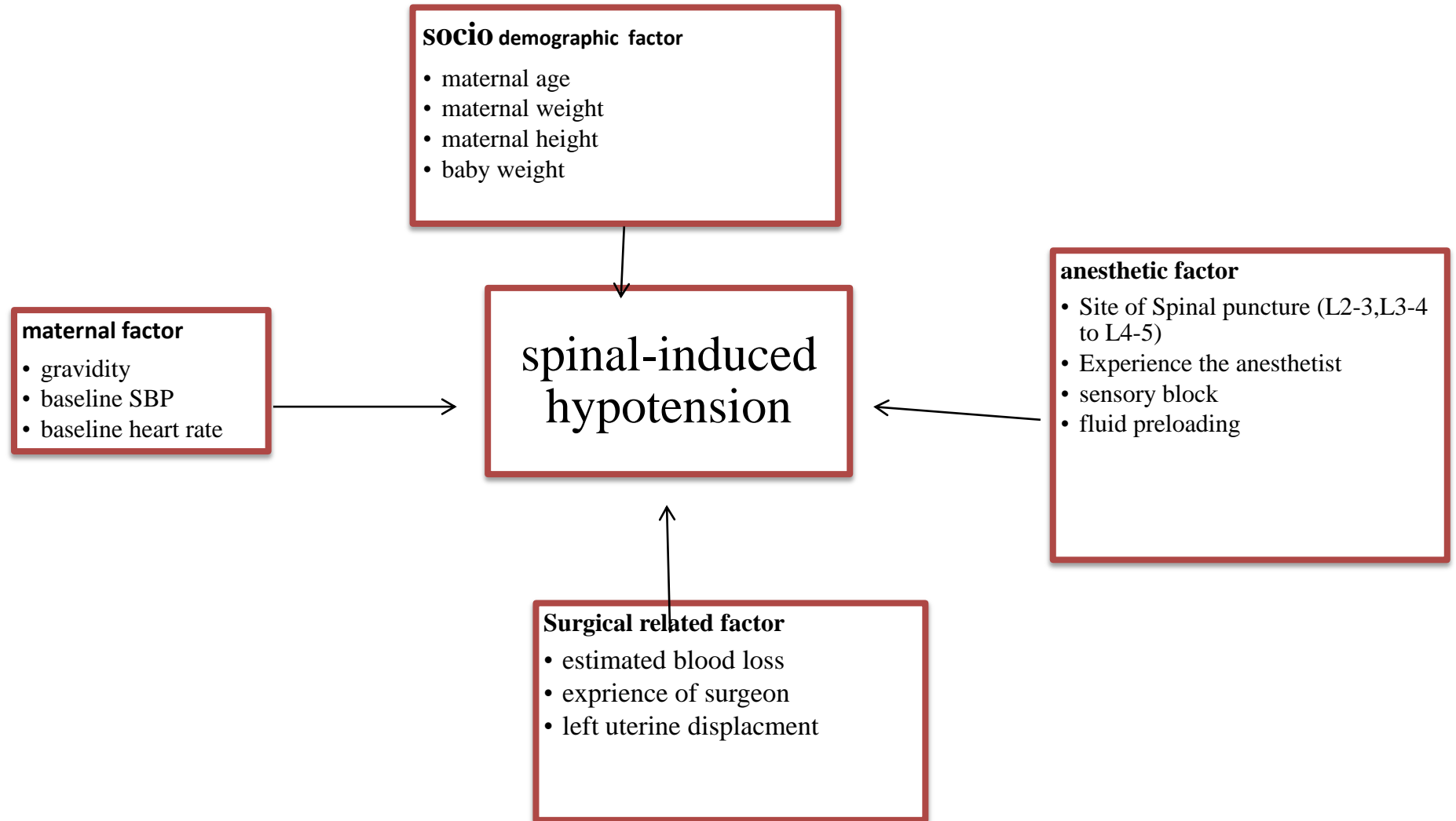


Figure 1 Conceptual frame work for assessing associated factors of SIH, developed from literature review.

3. Objective

3.1. General objective

To determine the incidence and associated factors for hypotension after spinal anesthesia during cesarean section at Gandhi memorial hospital, from January, to April, 2019

3.2. Specific objectives

- ❖ To determine the incidence of hypotension after spinal anesthesia during cesarean section
- ❖ To assess associated factors of hypotension after spinal anesthesia during cesarean section

4. Method and materials

4.1 Study area

The study was conducted at Gandhi memorial hospital found in Addis Ababa.

It was established in 1951 E.C and the hospital has been the only governmental maternity hospital in Ethiopia. It was named for memory of Mahatma Gandhi.

It is one of the thirteen governmental hospital found in Addis Ababa and governed by Addis Ababa health bureau. The hospital primarily gives services for women and children; the hospital provides gynecological, obstetric and reproductive health services including laparoscopic infertility surgery and sexual violence services.

In October 2016, the hospital established a neonatal unit and currently services as inpatient unit for at least 160 neonates per month. The hospital has 100 beds and 25 neonatal deliveries per each day. The hospital has two operation rooms and average number of 270 cesarean section was done per month. The study was conducted from January to April, 2019

4.2 Study design and study period

An institutional based cross sectional study was conducted from January to April 30, 2019

4.3 Populations

4.3.1 Source population

All pregnant mothers who delivered by cesarean section under spinal anesthesia at Gandhi memorial hospital.

4.3.2 Study population

All pregnant mothers who delivered by cesarean section under spinal anesthesia at Gandhi memorial hospital during study period.

4.4 Inclusion and exclusion criteria

4.4.1 Inclusion criteria

- ❖ All ASA class patients who underwent cesarean section under spinal anesthesia.

4.4.2 Exclusion criteria

- ❖ Failed spinal block

- ❖ Those who received combination of spinal and general or epidural anesthesia

4.5 Sample size determination and sampling procedure

4.5.1 Sample size determination.

The sample size was determined using the single population proportion method for the first objective which is incidence of hypotension after spinal anesthesia.

P=0.5 was used for calculation to get maximum sample size, 95% level of significance, 5% margin of error and 10% for incomplete or as contingency data was used as parameters. These parameters will be used to determine sample size using single population proportion formula

$$\text{Formula } n = \frac{(Z \alpha/2)^2 p(1-p)}{d^2}$$

With assumptions; Z=1.96, at 95% confidence level.

Margin of error =5%

$$n=384$$

Total sample size is **422**.

4.5.2 Sampling procedure

A study participant was selected using systematic random sampling technique using skip interval from the daily operation in the OT those patients undergone cesarean section. Situational analysis was done for one month, an average of 270 cesarean sections were done within a month under spinal anesthesia, at Gandhi memorial hospital.

Thus, 1080 cesarean section was done per the study period (4 months) the sampling interval; K will be determined using the formula: $K=N/n$; where, n = total sample size, N = population per 3 months. $K= 1080/422 \approx 2$ Therefore, the sampling interval was two and the first study participant (random start) was selected using lottery method from the daily cesarean section. Then, every second cases from the daily cesarean section was included in the study during the study period

4.6 study variables

4.6.1 Dependent variable

- ❖ Hypotension

4.6.2 Independent variables

Socio demographic

- ❖ Age
- ❖ Height
- ❖ Weight
- ❖ BMI of the mother
- ❖ Baby weight
- ❖ ASA class 1,2 and 3

Obstetric, surgical, preoperative and anesthesia related variables

- ❖ Duration of operation
- ❖ Types of vasoactive prophylaxis
- ❖ Preoperative maternal hemoglobin
- ❖ Base line blood pressure and heart rate
- ❖ History of hypertension
- ❖ Gravidity
- ❖ Intraoperative fluid volume
- ❖ Types of uterogenic agents
- ❖ Dose of oxytocin and Ergometrine
- ❖ Types of surgery
- ❖ Estimated blood loss
- ❖ Indication for cesarean section
- ❖ Left uterine tilt
- ❖ Amount of IV crystalloid preload administered
- ❖ Patient position during performance of the spinal induction
- ❖ Time interval between Spinal induction and skin incision
- ❖ Any intraoperative drugs used
- ❖ Spinal needle size
- ❖ Site of Spinal puncture (L2-3,L3-4 to L4-5)
- ❖ Experience the anesthetist

- ❖ Experience of the surgeon
- ❖ Type and dose of local anesthetic
- ❖ Sensory height block
- ❖ Adjuvants used with LA

4.7 data collection tool and procedure

Data was collected from selected study participants using pretested questionnaire. Questionnaire was adapted from different published literatures.(1)(34)(30)(27)(35) Data was collected from January to April 30, 2019. The questionnaire mainly addressed socio demographic variables (age, BMI,ASA status ,baby weight),maternal variables(gravidity, indication for C/History of hypertension preoperative Hgb and heart rate) anesthetic and surgical variables (LA dose, preload ,intraoperative fluids, time interval b/n spinal induction and skin incision, type of surgery (elective and emergency),estimated blood loss, surgeon and anesthetist experience, dose of uterogenic drug used, any pre and intraoperative drugs used adjuvants used and sensory block height).

Anesthesia management for cesarean section under spinal anesthesia in the study hospital is carried out by anesthetists. The data collection was done by four anesthetists after understanding the questionnaire and providing appropriate training. The completeness of data was checked every day by principal investigator.

4.8 Data processing and analysis

4.8.1 Data quality assurance

The questionnaires were prepared in English and one day training was given on the objectives and relevance of the study and brief Orientations on the assessment tools were provided for data collectors and supervisors by principal investigator before data collection. In case of missed measurement during intra-operative period, electronic data store of the monitoring equipment were recalled and back traced and data was filled. The questionnaire was pretested on 5% of the study population outside the study area (Zewuditu memorial hospital). Based on the pretest, questions were revised; edited and necessary modifications were made before actual data collection. Close checkup of data for completeness and consistency was done.

4.9 Data analysis

Data was checked for completeness, coded and then entered in to Epi Info version 7 and exported into SPSS version 20 for analysis. Descriptive statistics was used to calculate

frequencies and percentages of different variables and incidence of hypotension. Bivariate and multivariate logistic regression analysis were done to determine presence of associations between dependent and independent variables, and odds ratio with 95% confidence intervals was used to determine the degree of association between dependent and independent variables. Variables with a p-value less than 0.25 in the bivariate logistic regression analysis were considered for multivariable analysis. Multivariable analysis was performed to adjust for possible confounders and to come up with significant predictors. Level of statistical significance was declared at p-value less than 0.05. Both crude and adjusted odds ratio with 95% confidence interval were reported. The result will be presented by using text, table's, charts and graph

4.10 Operational definitions

Spinal induced hypotension: is the decline in blood pressure that occurs after the intrathecal administration of a local anaesthetic and mixtures of adjuvants

ASA classifications see at annex 3

Spinal induction: is the time of start to give local anesthetics in to subarachnoid space.

Failed spinal: spinal anesthesia was attempted, but no block resulted and inadequacy relating to the extent, quality, or duration of local anesthetic action for the proposed surgery.

Intraoperative period: the time period from arrival in to the operating theatre until the patient is transferred to the recovery room after end of surgery.

Left uterine tilt: putting the pregnant mother to left side at 15 or 30 degree by using pillow on the iliac crest area.

The level of sensory block: is loss of sharp sensation to pinprick or cold will be recorded bilaterally in the anterior axillary line or mid line clavicle.

Position of the patient: is the pregnant mother's position before performing spinal anesthesia and during spinal anesthesia is given.

Hypotension: is defined as systolic blood pressure below 100mmHg and reduction of systolic pressure of more than 20-30% from the baseline.(6)(18)

Base line blood pressure: blood pressure recorded before induction of spinal anesthesia.(37)

Pre loading: giving crystalloid fluid before induction spinal anesthesia.

4.11. Ethical Considerations

The study was conducted after approval by Addis Ababa University, Ethical review board to conduct the study. A legal letter was also be submitted to Gandhi memorial Hospital, where the study was take place. Verbal informed consent was be obtained from all parturient after full explanations of the goals and procedures of the study. After taking permission from the hospital the data collection was conducted

6 Results

6.1 Socio-demographic characteristics of respondents

During the study period 410 out of 422 clients were available for the final analysis with response rate of 97%. The mean (\pm SD) ages of the mother were 27.6 (\pm 4.23). Regarding the maternal height most of them are at height group of 160-169(63.7%) and around quarter of them are at height group of 150-159. All the study participants have been categorized in ASA class two. Most of the delivered neonates were weight range of 2500-3900 Grams.

Table 1 Socio-demographic characteristics of pregnant mothers who undergone C/S after spinal anesthesia, Gandhi memorial hospital Addis Ababa, Ethiopia, 2019 (n=410)

Variables	Category	Frequency	Percent
Age	15-25	120	29.3
	26-35	250	61
	>35	40	9.8
Height	150-159	97	23.7
	160-169	261	63.7
	170-179	52	12.7
	18.5-24.9	186	45.4
BMI	25-29.9	143	34.9
	\geq 30	81	19.8
ASA	class 2	410	100%
Baby weight	\leq 2.4	36	8.8
	2.5-3.9	314	76.6
	\geq 4	60	14.6

Of all clients in the research group clients, 153(37.3%) had base line blood pressure with 120-130mmHg which is relatively high.

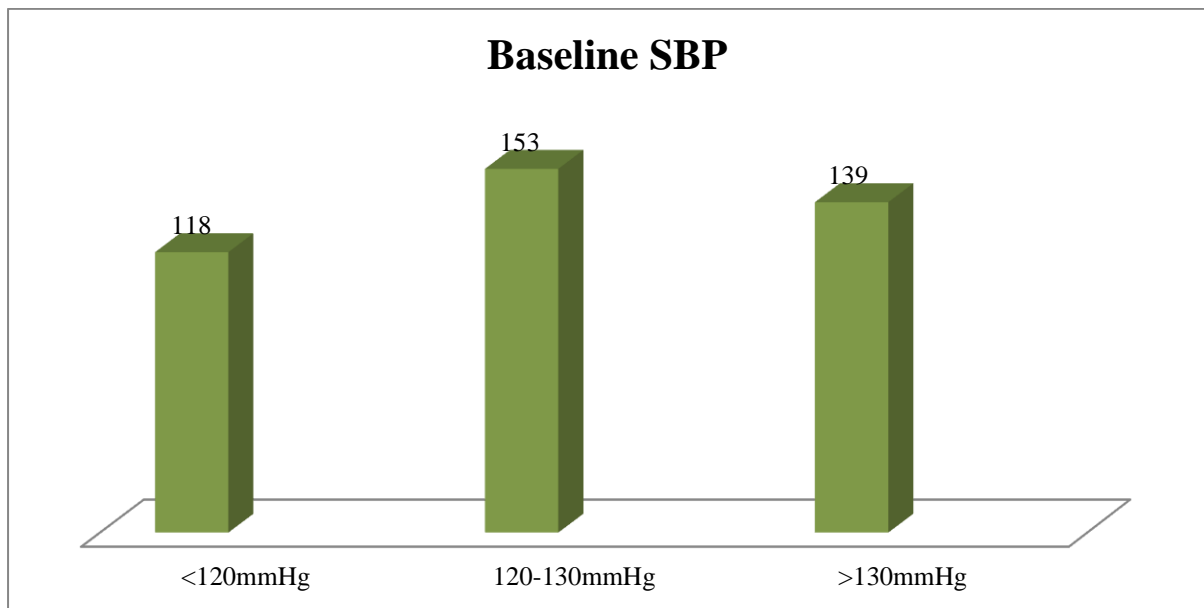


Figure 2. Baseline SBP of clients who underwent cesarean section after spinal anesthesia at Gandhi memorial hospital, Addis Ababa, Ethiopia, 2019.

6.2 Obstetric characteristics, medical and preoperative related history

Out of the total cases, 263(64.1%) of the pregnant mothers had a preoperative hemoglobin level of <11mg/dl and the rest were above 11g/dl. Regarding indication, most of the cesarean section was done due to Malpresentation of the fetus 130(31.7%) and 121(29.5%) was done for non-reassuring fetal status. Most of the cesarean sections have been done by resident three 195(47.6%) and resident four 123(30%).

Table 2 Obstetric characteristics, medical and preoperative related history who undergone caesarean section after spinal anesthesia at Gandhi memorial hospital Addis Ababa, Ethiopia , 2019.(n=410)

variable	Category	Frequency	Percent
Preoperative hemoglobin	Above 11g/dl	147	35.9
	Below 11g/dl	263	64.1
gravidity	One	104	25.4
	Two	145	35.4
	Three	108	26.3
	Four	36	8.8
	Five	17	4.1
Indication for C/S	Malpresentation	130	31.7
	Non reassuring fetal status	121	29.5
	Previous scar	79	19.3
	Previous scar and labour	36	8.8
	Other indication	44	10.7
Amount of crystalloids preloaded	< 500	227	55.4
	>500	183	44.6
Experience of surgeon	Resident two	77	18.8
	Resident three	195	47.6
	Resident four	123	30
	Senior	15	3.7
hypertension	No	359	87.5
	Yes	51	12.5

Of all clients who came for C/S, 51(12%) had hypertensive disorder. Gestational hypertension and preeclampsia accounts for 23(5.6%) and 22(5.4%) of types of hypertensive disorder respectively.

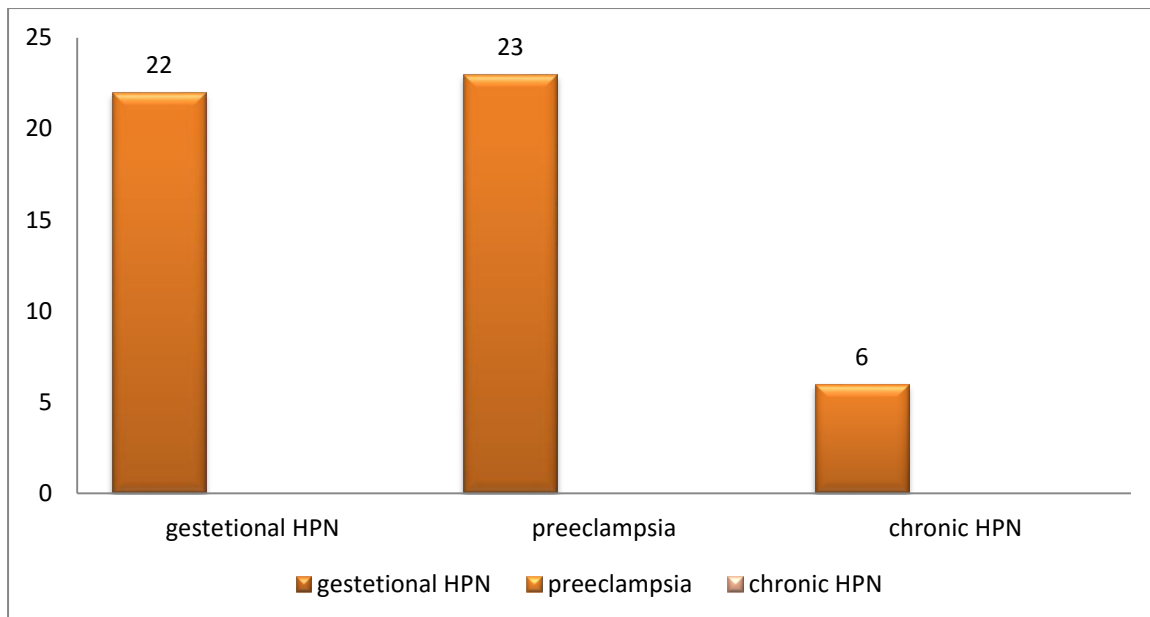


Figure 3 Types of hypertension who underwent cesarean section after spinal anesthesia at Gandhi memorial hospital, Addis Ababa, Ethiopia, 2019

6.3 Anesthesia characteristics and drug

In most cases (93.9%) lumbar puncture was done between L3 and L4. Different types of spinal needles were used, among which 170(41.5%) cases were done by using 23G needle and 162(39.5%) were done with 22G needle. All 410(100%) of the pregnant mothers who underwent cesarean section under spinal anesthesia were given 0.5% isobaric bupivacaine.

Majority of the anesthetists administered bupivacaine 0.5% with a dose of 12.5mg of local anesthetic. Fentanyl 25 mcg was added as an adjuvant for 48(11.7%) mothers who underwent cesarean section who had given local anesthetic (bupivacaine). 9(2.2%) of the clients received Propylactic Atropine. Sensory block height of below T6 was achieved on about half (202(49.7%)) of the clients. Most of the anesthetic procedures were performed by experienced anesthesia professionals above four years 93(22.7%) and 43(10.5%) of them were performed by anesthetists with four years of experience.

Table 3 Anesthesia characteristics and drug used for hypotension after spinal anesthesia during C/S at Gandhi memorial hospital Addis Ababa, Ethiopia, 2019. (n=410)

Variables	Category	Frequency	Percent
Site of spinal puncture	L2-L3	15	3.7
	L3-L4	385	93.9
	L4-L5	10	2.4
Spinal needle size	20G	17	4.1
	21G	38	9.3
	22G	162	39.5
	23G	170	41.5
	25G	23	5.6
Dose of LA with adjuvants(fentanyl)	10mg	31	7.6
	12.5mg	296	72.2
	15mg	35	8.5
	10mg &25mcg	48	11.7
Sensory height block	>T6	202	49.3
	≤T6	208	50.7
Adjuvants used with LA	No	362	88.3
	Yes	48	11.7
Any Proplactic vasoactive drug given	Yes	9	2.2
	No	401	97.8
Type and dose of adjuvants used with LA	fentanyl 25mcg	48	11.7
Experience of anesthetist	One year	74	18
	Two years	86	21
	Three years	51	12.4
	Four years	43	10.5
	Above four years	93	22.7
	Bsc students	63	15.4

6.4 Intra operatively used fluid and drug related variables

Majority of the study participant have received oxytocin 394(77.8%) for the sake of uterine contraction and the rest of them have received both oxytocin and Ergometrine together.

Regarding the intraoperative fluid majority of the study participant had taken greater than 1500ml of fluid 214(52.2%), and 117(28.5%) of the clients were given 1000-1500ml of crystalloid fluid. In most cases, 276(67.3%), greater than 6 minutes had elapsed before skin incision was started.

Table 4 intra operatively used fluid and drugs that had given for pregnant mothers who undergone after spinal anesthesia during C/S at Gandhi memorial hospital, Addis Ababa, Ethiopia, 2019. (n=410)

Variables	Category	Frequency	Percent
Types of uterogenic drugs used	Both	16	4
	Oxytocin	394	96
Amount of crystalloid intraoperative	<1000	79	19.3
	1000-1500	117	28.5
	>1500	214	52.2
Dose of uterogenic drugs used	Ergometrine 0.25mg and oxytocin 20IU	16	3.9
	Oxytocin 20IU	319	77.8
	Oxytocin 30IU	18	4.4
	Oxytocin 10IU	57	13.9
Intraoperative drug used	Yes	75	18.3
	No	335	81.7
Estimated blood loss	500-999	381	92.9
	≥1000	29	7.1
Time interval b/n spinal induction and skin incision	5	134	32.7
	>6	276	67.3

Among the total respondents majority of the mothers who underwent cesarean section were an emergency cases 237(57.8%) while the rests were an electives cases.

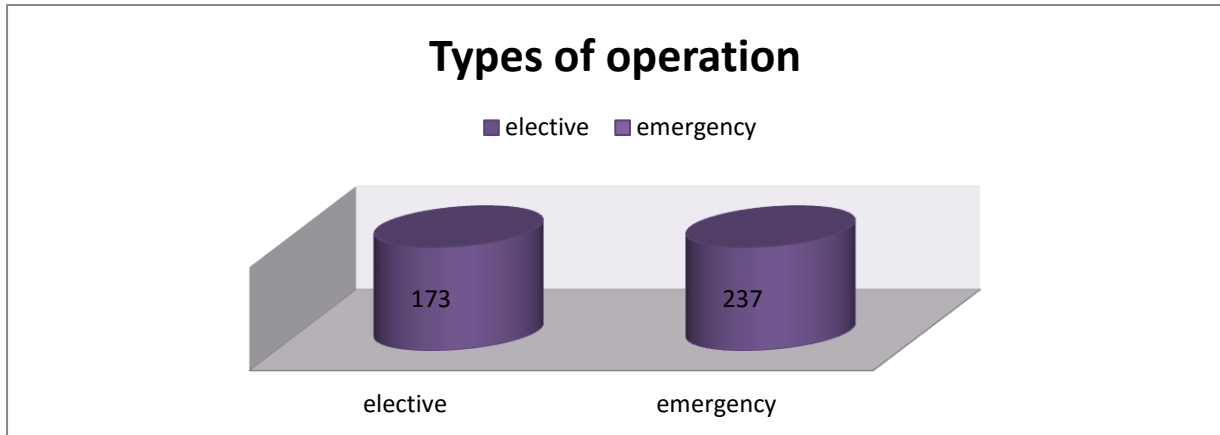


Figure 4 Types of operation who had cesarean section after spinal anesthesia at Gandhi memorial hospital, Addis Ababa, Ethiopia , 2019

From the total pregnant mothers who underwent cesarean section under spinal anesthesia the incidence of hypotension was 263 (64%).

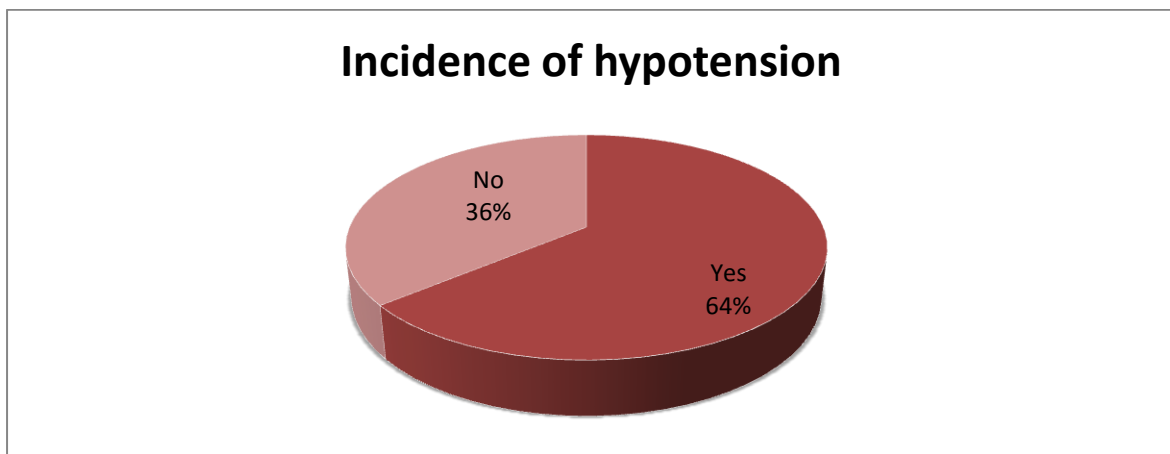


Figure 5 Incidence of hypotension among women’s who undergone cesarean section under spinal anesthesia, at Gandhi memorial hospital, Addis Ababa, Ethiopia , 2019.

6.4.1 Result of bivariate analysis

Socio-demographic factors associated with hypotension during cesarean section after spinal anesthesia in Gandhi memorial hospital, Addis Ababa Ethiopia, 2019

Binary logistic regression analysis was conducted to see the association between independent variables and dependent variable which is hypotension during Cesarean Section.

During Bivariate analysis, Mothers older than 35 years of age had 3 times [COR=3.633; 95%CI :(1.323-9.976) higher odds of developing hypotension compared to mothers with age group of 15-25 years. BMI greater than 30 is 2 times [COR=2.107; 95%CI :(1.176-3.777) more exposing to hypotension than with BMI range of 18.5-24.5. Regarding to baby weight range of 2.5-3.9kg [COR=3.236; 95% CI:(1.578-6.637) and weight greater or equal to 4kg [COR=6.396;95%CI:(2.558-15.993) had an association with hypotension .

Table 5 Bivariate analysis showing factors associated with hypotension among pregnant mothers who undergone C/S after spinal anesthesia, at Gandhi memorial hospital, Addis Ababa, Ethiopia, 2019

Variables	Category	Had hypotension		COR 95%CI	p-value
		No	Yes		
age	15-25	41	79	1	0.249
	26-35	101	149	0.766(0.486-1.206)*	
	>35	5	35	3.633(1.323-9.976)*	
BMI	18.5-24.9	76	110	1	0.338
	25-29.9	51	92	1.246(0.79-1.955)	
	>30	20	61	2.107(1.176-3.777)*	
Maternal height	150-159	36	61	1.243(0.625-2.471)	0.536
	160-169	89	172	1.417(0.773-2.600)	
	170-179	22	30	1	
Baby weight	<2.4	23	13	1	0.001
	2.5-3.9	111	203	3.236(1.578-6.637)*	
	>=4	13	47		

Preoperative and maternal related factors associated with spinal anesthesia induced hypotension for cesarean section after spinal anesthesia at Gandhi memorial hospital, Addis Ababa, Ethiopia, 2019.

According to the results of this study the baseline systolic blood pressure <120mmHg [COR= 3.998; 95% CI:(2.300-6.949) and in the range of 120-130mmHg [COR=2.214;95%CI:(1.378-3.557) were significantly associated with hypotension.

Table 6 Preoperative and maternal related factors associated with spinal anesthesia induced hypotension for cesarean section under spinal anesthesia at Gandhi memorial hospital, Addis Ababa, Ethiopia, 2019.

Variables	Category	Had hypotension		COR95% CI	P-value
		No	Yes		
Preoperative maternal hemoglobin	Above 11g/dl	45	102	1	0.099
	Below 11g/dl	102	161	0.696(0.453-1.070)*	
Base line SBP	>130mmHg	72	67	1	0.001
	120-130mmHg	53	103	2.214(1.378-3.557)*	
	<120mmHg	25	93	3.998(2.300-6.949)*	
Base line heart rate	60-80	25	48	1	0.475
	81-100	91	143	0.818(0.472-1.419)	
	>100	31	72	1.210(0.637-2.297)	
Gravidity	One	74	30	1	0.033
		61	84	1.791(1.047-3.065)*	
	Two	36	72	1.233(0.688-2.210)	0.481
	Three	13	23	1.394(0.625-3.108)	0.416
	Four	7	10	1.727(0.601-4.959)	0.310
Indication for C/S	Malpresentation	83	47	1	0.525
	Non reassuring fetal status	82	39	0.840(0.498-1.417)	
	Previous scar	53	26	0.866(0.480-1.563)	

Previous scar and labour	17	19	1.974(0.936-4.161)*	0.074
Other indication	28	16	1.009(0.496-2.054)	0.980

Anesthetic and surgical factors associated with hypotension among pregnant mothers who undergone cesarean section under spinal anesthesia at Gandhi memorial hospital, Addis Ababa ,Ethiopia, 2019

The less experienced anesthetist had strong association with hypotension. The interval between spinal induction and skin incision getting longer than six minutes 1.5 [COR=1.530; 95%CI :(1.000-2.340) times exposing to hypotension comparing with less than six minutes induction to skin incision. The sensory height block less than or equal to T6 [COR=3.358; 95%CI :(2.193-5.143) had strong association with hypotension.

Table 7 Anesthetic and surgical factors associated with hypotension among pregnant mothers who undergone cesarean section under spinal anesthesia at Gandhi memorial hospital, Addis Ababa ,Ethiopia, 2019

Variables	Category	Had hypotension		COR 95% CI	P-value
		No	Yes		
Sensory height block	>T6	100	102	1	
	<=T6	47	161	3.358(2.193-5.143)*	0.000
Experience of anesthetist	Above four years	51	42	1	
	Four years	22	21	1.59(0.562-2.391)	0.689
	Three years	16	35	2.656(1.295-5.450)*	0.008
	Two years	23	63	3.326(1.774-6.235)*	0.000
	One year	20	54	3.279(1.702-6.316)*	0.000
	BSC	15	48	3.886(1.912-7.897)*	0.000

	students				
Time interval b/n spinal induction and skin incision	≤5 minutes	57	77	1	
	>6 minutes	90	186	1.530(1.000-2.340)*	0.05
Estimated blood loss	500-1000	243	138	1	
	>1000	20	9	1.262(0.559-2.848)	0.575
Experience of surgeon	Resident two	29	48	1.892(0.621-5.764)	0.262
	Resident three	68	127	2.134(0.742-6.138)*	0.159
	Resident four	42	81	2.204(0.748-6.495)*	0.152
	Senior	8	7	1	

***P< 0.25 COR crude odds ratio**

6.4.2 Results of multivariable logistic regression analysis

Factors associated with hypotension for cesarean section under spinal anesthesia in Gandhi memorial hospital, Addis Ababa, Ethiopia, 2019

After excluding variables which doesn't fit for the model and using P-value >0.25 in likelihood ratio test multivariate analysis was performed.

In comparison to mothers who delivered at age range of 15-25, those mothers who delivered at age range of 26-35 [AOR=0.522; 95%CI :(0.281-0.972)] had less risk of developing hypotension. Neonates delivered by cesarean section with weight range of 2.5-3.9kg were three times AOR=3.440; 95% CI:(1.441-8.211) more likely cause to develop hypotension in comparison with weight of less than 2.5kg. Those mothers with the baseline systolic blood pressure less than 120mmHg had 5 times more prone to develop hypotension AOR= 5.527; 95%CI: (2.695-11.336) than with systolic baseline blood pressure greater than 130mmHg. On other hand, mothers with systolic blood pressure at range of 120-130mmHg were 3 times

more likely to have hypotension in comparison with greater than 130mmHg AOR=3.583; 95%CI: (1.980-6.485).

Pregnant mothers who had cesarean section under spinal anesthesia with sensory block height \leq T6 had two times high risk of developing hypotension in comparison with greater than T6 AOR= 2.272;95%CI: (1.362-3.788).

The result showed as the time interval between spinal induction and skin incision becomes longer than six minutes there is 1.75 fold increase in development of hypotension in comparison with performed less than equal to five minutes AOR=1.758;95%CI: (1.022-3.024).The odd of a mother developing hypotension was 2.7 times higher when the procedure was performed with three years' experienced anesthetist AOR=2.746; 95%CI: (1.157-6.521). the clients were 4.5 times more likely to develop hypotension when spinal anesthesia was delivered by anesthetist who had one year clinical experience.

Table 8 Multivariate analysis showing factors associated hypotension among pregnant mothers who undergone C/S under spinal anesthesia, at Gandhi memorial hospital, Addis Ababa, Ethiopia, 2019.

Variables	Category	Had hypotension		COR 95% CI	AOR 95% CI	p-value
		No	Yes			
Age	15-25	41	79	1	1	
	26-35	101	149	0.766(0.486-1.206)	0.522(0.281-0.972)**	0.040
	>35	5	35	3.633(1.323-9.976)	1.455(0.424-4.993)	0.551
Baby weight	\leq 2.4kg	23	13	1	1	
	2.5-3.9kg	111	203	3.236(1.578-6.637)	3.440(1.441-8.211)**	0.005
	\geq 4kg	13	47	6.396(2.558-15.993)	4.957(1.563-15.722)**	0.007
Baseline SBP	>130mmHg	72	67	1	1	
	120-130mmHg	53	103	2.214(1.378-3.557)	3.583(1.980-6.485)***	0.0001
	<120mmHg	25	93	3.998(2.300-6.949)	5.527(2.695-11.336)***	0.0001

Sensory height block	≥T6	100	102	1	1	
	<T6	47	161	3.358(2.193-5.143)	2.272(1.362-3.788)**	0.002
interval b/n anesthesia and skin incision	≤5 minutes	57	77	1	1	
	>6 minutes	90	186	1.530(1.000-2.340)	1.758(1.022-3.024)**	0.041
Anesthetist experience	Above five year	51	42	1	1	
	Four years	22	21	1.59(0.562-2.391)	0.918(0.396-2.127)	0.842
	Three years	16	35	2.656(1.295-5.450)	2.746(1.157-6.521)**	0.022
	Two years	23	63	3.326(1.774-6.235)	4.527(2.101-9.756)***	0.0001
	One year	20	54	3.279(1.702-6.316)	4.501(1.966-10.306)***	0.0001
	BSC students	15	48	3.886(1.912-7.897)	4.589(1.964-10.724)***	0.0001

Statistically significant ** P < 0.05, ***P<0.001, AOR adjusted odds ratio,

7. Discussion

In our study the overall incidence of hypotension among mothers who underwent cesarean section under spinal anesthesia is 64%. Almost similar result was found in Bangkok Thailand with incidence rate of 65.1%.⁽³⁰⁾ In a research done in Thailand Mahidol university the incidence rate was higher than our study 76.7%.⁽³⁴⁾ On other study at chulalongkom university Bangkok the incidence rate was lower than our finding 52.1% and study done in Germany shows an incidence of hypotension was 56.5%.^(14,27) while the incidence of hypotension was 38% as study done in Spain.⁽³⁷⁾

The possible reason for different incidence rate will be: Using different type of definition for hypotension, clinical setup and method of data collection.

The Factors which had an association with hypotension was assessed by multivariate logistic regression. In this study the associated factors are, baby weight, baseline systolic blood pressure, sensory height block, time interval between spinal induction and skin incision and experience of anesthetists were identified as a factor associated with hypotension and pregnant mothers in age group of 26-35 years old were less likely to cause hypotension compared to pregnant mothers with age group of 15-25 years old.

In our study we found pregnant mothers in age group of 26-35 years were 48% less likely to cause hypotension compared to pregnant mothers with age group of 15-25 years old. Our finding is different from the results stated by other studies.^{(29,30),(27)} The possible reason may be due to socio demographic characteristics. Additionally this needs further research.

The weight of the neonates have significant association with hypotension is found in our study; neonates which born with larger weight has six folds risk of developing hypotension than low birth weight. This study is in line with research done in Spain in which the weight of the newborn was identified as a risk factor for developing hypotension when it is higher than 3900 gram. ⁽³⁷⁾ there is also other study which support our finding that was done in America as higher birth weight increase the risk of maternal hypotension.⁽²¹⁾ The possible reason will be as baby weight is larger a higher risk of increase pressure of gravid uterus upon the inferior venacava and major arteries compression. That results in decrease venous return leads to reduction in preload which predispose to hypotension.

Another factor associated with hypotension was baseline systolic blood pressure <120mmHg with (OR, 5.527) and 120-130mmHg with (OR, 3.583) five and three folds of developing

hypotension in reference with ≥ 130 mmHg. Our finding is consistent with The study done in Bangkok that stated the risk of hypotension in patients with baseline SBP less than 130mmHg that means less than 120mmHg and 120-130mmHg was significantly increased (34) and according to Randall L.carpenter.et.al showed that baseline systolic blood pressure less than 120mmHg has 2-fold increase in the odd of developing hypotension with which supports our finding.(35) The reason behind this will be a higher baseline blood pressure has high safety of margin, in that systolic blood pressure decreases 20-30% from the baseline and blood pressure remains above 100mmHg. The other expected reason will be those clients with low baseline systolic blood pressure might have low baseline systemic vascular resistance so vasodilation will increase after spinal block

The sensory height block higher than T6 with (OR 2.272) was statically significantly associated with risk of developing hypotension. This study is consistent with different research. Which was done in different country. Research done in chulalogkorn university Bangkok the sensory block height greater than T5 with (OR=1.94)(14) in addition our study in agreement with study done by pitchya ohpasanon et al. sensory block height \geq T5 was identified as a factor for hypotension.(30) The possible explanation will be The sensory block height is to be resulted from blockade of the sympathetic nervous system. Furthermore higher sensory levels of analgesia correlated with relatively greater reduction in systolic blood pressure.(14) The physiological explanation is that the higher the level of sensory blockade, the more autonomic blockade happen, results more vasodilation and more hypotension. (35)(38)

The risk of hypotension has strong association with less experience of anesthetist, in our study the risk of hypotension was increase as the experience of anesthetist less when compared to those procedures who underwent cesarean section more experienced greater than four years. The research done in Ethiopia, Addis Ababa in two hospitals strongly support our study.(1) The reason may be due to as someone skill, performance and identifying the risk mothers improves when getting experienced.

There is also other finding which has an association with hypotension in our study. Which is the time interval between spinal induction and skin incision, when there is a delay between the time interval of spinal induction and skin incision becoming longer 1.5–fold increase in the odds of developing hypotension. The possible explanation may be the pregnant mother

will be on supine position after spinal induction so a long time in supine position may have aorto-caval compression and the sympathetic blockade by spinal anesthesia. so further research has to be needed for confirmation.(8)(39)

Strength and limitations of the study

Strengths

- The sample size is relatively large.
- The study also includes a new finding in relation with hypotension which is interval between spinal induction and skin incision.

Limitation

- Since speed of injection of local anesthetic is one factor, but difficult to measure in our set up.
- Lack of similar published topic literature in Ethiopia and Africa.

8 Conclusion and recommendation

8.1 Conclusions

In our study the incidence of spinal induced hypotension is 64%. I found different associated factors for incidence of hypotension during cesarean section under spinal anesthesia those are the experience of anesthetist, birth weight, baseline systolic blood pressure, sensory height block, interval between spinal induction and skin incision. And maternal age at range of 26-35 years of old have less risk of hypotension.

Having this knowledge of the associated factors for spinal induced hypotension might help in the day to day routine to increase the anesthetist's vigilance regarding those mothers at risk for hypotension.

8.2 Recommendations

Based on the findings of the present study, the following recommendations are forwarded

For anesthetist

- ❖ The incidence of hypotension shows the size of the problem, so necessary precaution should be used to reduce this incidence and risk factors for management of patients after spinal block is the key to success.
- ❖ Appropriate preparation should be done for pregnant mother who come for cesarean section with baby weight of greater than four kilograms.
- ❖ It is good to work together as one more experience anesthetist with less experienced.
- ❖ Reduce the deleince of the time interval between spinal induction and skin incision.
- ❖ Precaution should be given for pregnant mothers whose baseline systolic blood pressure less than 120mmHg.

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Annex 1:

INFORMATION SHEET

Title of the Research Project: THE INCIDENCE AND ASSOCIATED FACTORS FOR HYPOTENSION FOR CESEREAN SECTION UNDER SPINAL ANESTHESIA

Name of Principal Investigator: Temesgen Mamo

Name of the Organization: Addis Ababa University, College of Medicine and health science. Department of Anesthesia

Introduction: Greetings! My name is Temesgen Mamo. I am a student at Addis Ababa University Department of Anesthesia College of Medicine and Health Sciences in Masters of Science (MSc) in clinical anesthesia. As part of this degree I am undertaking a research Project “The incidence and associated factors of hypotension for cesarean section under spinal.”

Purpose of the Research Project: The aim of this study is to determine the incidence and associated factors of hypotension for cesarean section under spinal anesthesia in Gandhi memorial hospital. The information gained from this research will be used to make clinical recommendations.

Procedure: The data collection will be conducted in Gandhi memorial hospital. Standard questioner was prepared to collect necessary information from the written document, working anesthetist during data collection and from the monitoring device used in the operation room.

Risk and /or Discomfort: the data will be taken from the anesthetist, anesthesia chart and vital sign monitoring device, so it was not impose any harm on patients.

Benefits: The study has no direct benefit for those caesarian section delivery clients whose information is abstracted but indirectly beneficial if the result utilized by clinicians. Gandhi memorial hospital will get the result of the study.

Confidentiality: During data collection the patients name and card number was not taken in the questionnaire. All questionnaires' collected was kept confidential. The information collected was used only for research purpose. The thesis will be submitted to Addis Ababa University Department of Anesthesia College of Medicine and Health Sciences and displayed in the University Library and website. This study is also intended to be submitted for publication in scholarly journals.

Right to Refusal or Withdraw: Approval of the manager of the hospital and participant will be required to start data collection.

Person to contact: If you have any further questions or would like to receive further information about the project, please contact

1. Temesgen Mamo (principal investigator):+251912107804

Luelayehu Akalu -Assistant Professor (advisor)

Selam Jima (B.Sc. M.Sc. lecturer in anesthesia)(advisor)

Thank you for reading the information sheet and asking any questions that you have might have had.

Annex 2:

Consent form (English version)

Dear participant:

Hello, my name is _____ and I am a data collector for research aimed to determine the incidence and associated factors for spinal induced hypotension during cesarean section under spinal anesthesia in Gandhi memorial hospital, Ethiopia. Since the study is not linked with any financial aid there is no direct incentives paid as a result of you taking part in the study. However, your legitimate participation in filling the questionnaire with real information is very important and highly appreciated.

I would like to assure you, that your name will not be written on this form and all the information gathered will be kept strictly confidential.

You can decide whether you want to take part in the questionnaire or not. I would like to assure you that there are no negative impacts you face because of taking part in the study. Please feel free to ask any questions data collector nearby.

You can also contact principal investigator with address below:

1. Temesgen Mamo: +251912107804

. **Luelayehu Akalu Assistant Professor (Advisor)**

Selam Jima (B.Sc. M.Sc lecturer in anesthesia)(Advisor)

Annex 3: ASA PHYSICAL STATUS CLASSIFICATION SYSTEM

Last approved by the ASA House of Delegates on October 15, 2014

ASA Classification	Definition	Examples, including, but not limited to:
ASA 1	A normal healthy patient	Healthy, non-smoking, no or minimal alcohol use
ASA 2	A patient with mild systemic disease	Mild diseases only without substantive functional limitations. Examples include (but not limited to): current smoker, social alcohol drinker, pregnancy, obesity (30<BMI<40), well controlled DM/HTN, mild lung
ASA 3	A patient with severe systemic disease	Substantive functional limitations; One or more moderate to severe diseases. Examples include (but not limited to): poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis, premature infant PCA < 60 weeks, history (>3 months) of MI, CVA, TIA, or CAD/stents
ASA 4	A patient with severe systemic disease that is a constant threat to life	Examples include (but not limited to): recent (<3months) MI, CVA, TIA, or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, sepsis, DIC,ARD or ESRD not undergoing regularly scheduled dialysis

ASA 5	A moribund patient who is not expected to survive without the operation	Examples include (but not limited to): ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ/system dysfunction
ASA 6	A declared brain-dead patient whose organs are being removed for donor purposes	
The addition of “E” denotes Emergency surgery:(An emergency is defined as existing when delay in treatment of the patient would lead to a significant increase in the threat to life or body part)		

Annex 4:

Data collection Questioner

Questioner developed for collection of data for the study “the incidence and associated factors for spinal induced hypotension during cesarean section under spinal anesthesia in Tikur anbesa specialized hospital”

Part one: Socio-demographic

Serial number	questions	response	Code
101	Age of the parturient		
102	Height of parturient		
103	Weight of parturient		
104	BMI		
105	Weight of baby		
106	ASA status	Class 1	1

		Class 2	2
		Class 3	

Part two: pre-operative data

Serial number	Question	Response	Code
201	Base line heart rate	(.....)b/m	
202	Base line blood pressure	(.....)mmHg	
203	Preop-hemoglobin		
204	Gravidity	One	1
		Two	2
		Three	3
		Four	4
		Above specify	5
205	History of hypertension	Yes	1
		No	2
206	If yes	Chronic hypertension	1
		Super imposed HPN	2
		Preeclampsia	3
		Gestational HPN	4
207	Types of operation	Elective	1
		Emergency	2
208	Indication of the operation	Previous scar	1
		Malpresentation	2
		Post term pregnancy	3
		Non reassuring fetal status (includes bradycardia)	4
		Placenta praveia	5

		Cervical arrest	6
		CPD	7
		Specify others	8

Part three: surgical and anesthetic factors

Serial number	Questions	Response	Code
301	Duration of operation		
302	Estimated blood loss	500- 1000ml	1
		>1000ml	2
303	Left uterine tilt	YES	1
		NO	2
304	Spinal needle size	21G	1
		23G	2
		25G	3
305	Site of spinal puncture	L2-L3	1
		L3-L4	2
		L4-L5	3
306	Type of local anesthetic	Bupivacaine 0.5%	1
		Lidocaine 5%	2
307	Dose of local anesthetic	10mg	1
		12.5mg	2
		Other specify	3
308	Sensory block height	Up to T10	1
		Up to T8	2
		Up to T6	3
		Above T6	4
309	Proplactic Vasoactive drugs given	Yes	1
		No	2
310	If yes write type of		

	drug		
311	Types of uterogenic agents	Oxytocin	1
		Ergometrine	2
312	Route of oxytocin	IV bolus	1
		Infusion	2
313	Patient position during spinal induction	Supine	1
		Lateral	2
314	Amount of crystalloids preload	500ml	
		1000ml	
315	Intra operative fluid volume	1000ml	1
		2000ml	2
		3000ml	3
316	Time interval between spinal puncture and incision		
317	Adjuvants used	yes	1
		no	2
318	Experience of anesthetist	1 year	1
		2 year	2
		3 year	3
		4 year	4
		>4 year	5
		BSC students	6
319	Experience of surgeon	Resident 1	1
		Resident 2	2
		Resident 3	3
		Resident 4	4
		Senior	5

Part four: intra operative vital sign

<i>Vital sign</i>	<i>Base line</i>	<i>At induction</i>	5 th min	10 th min	15 th min	20 th min	25 th min	30 th min	35 th min
SBP									
DBP									
MAP									

Vital sign	40 th min	45 th min	50 th min	55 th min	60 th min
SBP					
DBP					
MAP					

Name of data collector..... signature

Name of supervisor..... Signature

