COMPARISON OF FETO-MATERNAL OUTCOME OF GENERAL AND SPINAL ANESTHESIA AMONG PREGNANT MOTHERS WHO UNDERWENT CATEGORY ONE CAESEREAN SECTIONS –A PROSPECTIVE CROSS-SECTIONAL STUDY AT JIMMA UNIVERSITY MEDICAL CENTER, JIMMA, ETHIOPIA 2022.

THESIS PAPER TO BE SUBMITTED TO DEPARTMENT OF ANESTHESIA, FACULTY OF MEDICAL SCIENCE, INSTITUTE OF HEALTH IN THE PARTIAL FULFILLMENT FOR MASTER OF SCIENCE DEGREE IN ADVANCED CLINICAL ANESTHESIA

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COMPARISON OF FETO-MATERNAL OUTCOME OF GENERAL AND SPINAL ANESTHESIA AMONG PREGNANT MOTHERS WHO UNDERWENT CATEGORY ONE CAESEREAN SECTIONS –A PROSPECTIVE CROSS-SECTIONAL STUDY AT JIMMA UNIVERSITY MEDICAL CENTER, JIMMA, ETHIOPIA 2022.

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Abstract

Background: Category one cesarean section is performed in the most urgent conditions for the fetus or mother and sometimes in both cases. Now-a days, the practice of anesthesia for emergency cesarean sections is becoming spinal over general anesthesia due to adverse feto-maternal outcome.

Objectives: To compare feto-maternal outcomes of general and spinal anesthesia during category one cesarean deliveries at Jimma University Medical Center, 2022.

Methods: A prospective comparative cross-sectional study was conducted at Jimma University Medical Center from August to October, 2022. The study included 72 cases of category one caesarean sections during the study period. Indications for category one cesarean delivery, DDI, maternal vital signs, intraoperative blood loss and need for blood transfusion and ICU admissions were noted to compare maternal outcomes. On the other hand, for comparison of newborn outcomes, variables such as APGAR scores at one and five minutes, need for bag mask ventilation, intubation and NICU admissions were used. Independent sample student's t-test was used for comparison of normally distributed continuous data and Mann Whitney U test for non-normally distributed data. Chi-square and Fisher Exact tests were used for comparison of categorical data. P-value less than 0.05 was used to show statistically significant difference on outcomes between groups.

Result: The ages of the participants were comparable between general and spinal anesthesia, in which the mean was 27.86± 5.42 and 26.27± 6.77 years, respectively; p= 0.344. Baseline maternal vital signs were also not significantly different statistically between groups. DDI and one and five minute Apgar scores were significantly different between groups. There also was statistically significant difference between groups regarding blood loss and requirement for transfusion of blood products. There was no significant difference between general and spinal anesthesia regarding neonatal and maternal death statistically.

Conclusion: General anesthesia may be considered faster than spinal anesthesia during emergency caeserean section deliveries, but associated with fetal and maternal morbidity compared to spinal anesthesia. Spinal anesthesia might be better over general anesthesia to have a favorable outcome if and only if there are no contraindications.

Key Words: Category One, Cesarean Section, General Anesthesia, Spinal Anesthesia, Feto-maternal outcome

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Abbreviations

ACOG: American College of Obstetrician and Gynecologists

APGAR1: Activity, Pulse, Grimace, Appearance and Respiration at 1 minute

APGAR5: Activity, Pulse, Grimace, Appearance and Respiration at 5 minute

ARDS: Acute Respiratory Distress Syndrome

ASA- PS: American Society of Anesthesiology- Physical status

BMV: Bag and Mask Ventilation

BP: Blood Pressure

C/S: Caeserean Section

DDI: Decision to Delivery Interval

FFP: Fresh Frozen Plasma

FHR: Fetal Heart Rate

GA: General Anesthesia

HELLP: Haemolysis, Elevated Liver enzymes, and Low Platelet

HR: Heart Rate

ICU: Intensive Care Unit

IV: Intravenous

JUMC: Jimma University Medical Center

MAP: Mean Arterial Pressure

NICE: National Institute for Health and Care Excellence

NICU: Neonatal Intensive Care Unit

PRBCS: Packed Red Blood Cells

RA: Regional Anesthesia

RCOA: Royal College of Anesthetists

RCOG: Royal College of Obstetrician and Gynecologists

RR: Respiratory Rate

RSGA: Rapid Sequence General Anesthesia

RSSA: Rapid Sequence Spinal Anesthesia

SA: Spinal Anesthesia

SCBU: Special Care Baby Unit

SPO2: Peripheral Arterial Oxygen Saturation

TTD: Time to Delivery

TTI: Time to Incision

UK: United Kingdom

WHO: World Health Organization

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Chapter 1: Introduction

1.1. Background

World Health Organization (WHO) recommended the optimal Caesarean section rate should be between 5 and 15%. However, it is significantly increasing without a known reason and constitutes approximately 25% of all births in USA (1). According to the most recent estimates, the average global rate of CS is 18.6%, ranging from 6.0% to 27.2% in the least and more developed regions, respectively. The lowest rates of CS are found in Africa (7.3%) and more specifically in Western Africa (3%) (2). The pooled estimated prevalence of Caesarean section in Ethiopia was 29.55% (3). According to the 2016 Ethiopia Demographic and Health Survey, the rate of C-section was 21.4% in Addis Ababa (4).

Indications for saving fetal or maternal life are usually emergency, but there is a difference in the degree of its urgency. The four-point classification of urgency of CS used by the National Confidential Enquiry into Perioperative Deaths classify urgency of caeserean section as in the following: Category 1 – when there is an immediate threat to life of the mother or fetus, Category 2 – when there is maternal or fetal compromise, but not immediately life-threatening, Category 3 – when there is a need of early delivery but no maternal or fetal compromise, Category 4 – when delivery is to be done at a time to suit the woman and maternity team (5). The preferred anesthetic technique for all categories except category one is regional anesthesia most commonly spinal anesthesia (5).

Indications of caeserean sections that could be considered as category-1 includes persistent fetal bradycardia and tachycardia, placental abruption, placenta Previa with hypovolemia, cord prolapse, severe oligohydramnios, HELLP syndrome, previous uterine scar in active labor, breech presentation of second twin, ARDS and failed instrumental delivery which imposes immediate threat to both the mother and fetus if delivery is delayed beyond 30 minutes of decision time according to RCOG recommendations (6,7)

General anaesthesia refers to the loss of ability to perceive pain associated with loss of consciousness produced by intravenous or inhalation anaesthetic agents. For caesarean section, this involves the use of IV drugs for induction, tracheal intubation facilitated by suxamethonium, positive-pressure ventilation of the lungs with a nitrous oxide/oxygen mixture plus a volatile agent, and a muscle relaxant (8). General anesthesia is useful in the facilitation of a rapid

procedure in emergencies and helps to render the parturient unconscious intraoperatively and lessen stress from surgical conditions. However, it is associated with unwanted side effects such as the possibility of aspiration pneumonia, maternal awareness during the operation due to inadequate anesthesia, failed intubation, and respiratory complications in the mother and newborn. Additionally, many intravenous and inhalational anesthetic agents can cross the placental barrier and enter fetal circulation and may cause sedation or respiratory depression of the newborn. When supplemented with halogenated volatile agents, general anaesthesia has also been associated with a greater risk of maternal blood loss compared with regional anaesthesia (9).

Regional anesthesia is the most commonly used and preferred technique of anesthesia for cesarean. The advantages of using regional anesthesia include reduced complications associated with general anesthesia and promotion of initial bonding between the mother and the baby (because the mother is awake during the operation) (10). Recently, spinal anesthesia has been the most preferred anesthesia for cesarean section because of its rapid onset, effectiveness, and lower requirement for local anesthetics; however, it is associated with a higher incidence of arterial hypotension (11). Spinal anesthesia using small amounts of local anesthetics is less likely to cause maternal systemic toxicity or total spinal anesthesia.

Studies show varying results for neonatal outcome with SA and some with GA (12). Study done in the UK on the mode of anesthesia for category 1 C/S showed that the DDI for a GA CS was eight minutes rapid than RA groups and babies born by category 1 GA CS were significantly more likely to have an Apgar score < 7 at five minutes, to require bag/mask ventilation for > 60 seconds and to be admitted to a neonatal intensive care nursery (13).

1.2. Statement of the Problem

The type of anaesthesia used and the care with which administered is an important determinant of the outcome of caesarean section (14). There are a large number of studies done to compare the fetal and /or maternal outcomes under general versus spinal anesthesia for elective and non-urgent emergency caeserean sections, but there is limited studies done regarding category one caeserean sections.

In category one Caeserean Section surgery, rapid sequence general anesthesia is commonly used because this technique is assumed to be faster to perform than SA (15). However, this anesthesia technique is currently being challenged due to risk of hypoxia, aspiration, and controversies with the technique, the choice, and doses of drugs (16). Rapidly performed spinal anesthesia will become a more acceptable option in category-1 CS (5).

The relative risk of maternal death for category-1 caesarean section was observed to be fifteen times that of category-3 caesarean section (15). Regarding life-threatening complications, women who received general anaesthesia demonstrated higher proportions of sepsis and transfusions of PRBCs and FFP on the day of delivery than those who received regional anaesthesia (17). Category-1 caesarean section for fetal indications in women with predicted difficult tracheal intubation presents a unique challenge to anesthetists (18). In this type of conditions, the decision to proceed either under general or spinal anesthesia is the most challenging scenario. This is because, in either type of anesthesia there will be the unwanted risks for both mother and newly born babies.

Spinal anesthesia is safe both for mother and fetus, but even without contraindications, certain factors that prolong decision to delivery intervals will preclude the choice of spinal anesthesia for those most urgent category one C/S cases. According to the findings of researches on DDI and association to fetal outcomes there is controversy regarding the clinically significance influence. Additionally, anesthesia type is not the only factor that can prolong DDI, but also a number of factors are identified. Availability of materials, time of decision, type of anesthesia, and decision to anesthesia time, experience of surgeons, and experience of anesthetists had a statistically significant influence on DDI (19).

Caeserean sections done under general anesthesia is associated with greater feto-maternal morbidity and mortality. Mothers for whom operations were done under general anesthesia were 2.81 times more likely to have maternal complications compared to mothers for whom operations were done under spinal anesthesia. The risk of low APGAR score at 5 min was increased in babies born under general anesthesia as compared with babies born under Spinal anesthesia (20).

Up to the best of my knowledge and current searching result for literatures regarding my topic, little is known about category one cesarean section and anesthesia. Because studies done for emergency caesarean deliveries cannot be concluded in general for this category one group of patients as the nature of urgency of emergency caesarean section is different. Those groups of patients are unique and demand meticulous attention in choosing management options for favorable outcome of both mother and fetus. Therefore, studying the reality behind category one cesarean section and anesthesia effect will help one step advancement of anesthesia practice in our setup where there is usually a dilemma and misunderstanding between anesthetists and obstetricians regarding the anesthesia options for those group of patients.

In our setting there is no clearly stated principles of practicing anesthesia for obstetrics patients undergoing caesarean delivery even for emergency cases. Emergency caesarean section has four classes of urgency in which category one is the most urgent condition either for fetus or mother. In such situation practicing what is routinely done will not give guarantee for better outcome and it is important knowing the fetal and maternal outcomes of general and spinal anesthesia after such most urgent caesarean deliveries. Therefore, the aim of this research is to compare fetal and maternal outcomes between general and spinal anesthesia after category one cesarean section.

1.3. Significance of the study

Undertaking this research will benefit mothers and newly born babies by limiting complications related with the use of anesthesia for caeserean delivery. It will limit the cost of mother's expense for buying complex drugs and materials. Knowing the effect of anesthesia type on feto-maternal outcome will help to have safe and less risk anesthesia plan for those expected to undergo category one emergency caeserean delivery. For health professionals, it will help to have confidence in selecting anesthesia for mothers with category one C/S indications. It will also help to minimize risk of exposure and theatre pollution with waste anesthetic gases from traditional use of GA for emergency caeserean delivery.

In an emergency scenario, the communication between the obstetrician and the anaesthetist plays a vital role in ensuring the safety of mother and baby. It is common to be faced with the dilemma of whether to allow time for a RA over giving a GA. Notwithstanding the maternal risks associated with a GA, if more was known about neonatal risks (especially short-term respiratory morbidity), this might help inform the decision-making and improve the way the care is provided to both mothers and babies in urgent situations.

The result of this study will help the institution in developing local guidelines for safe practice of anesthesia for emergency caeserean deliveries and it will help to find out what is being practiced. It will help also to minimize unnecessary use of GA for every emergency parturients by helping to identify feto-maternal outcomes of both GA and RA specifically spinal anesthesia. The study will also help as a base for future researchers regarding the study problem.

Chapter 2: Literature Review

Emergency Caesarean section (EmCS) may be performed for fetal or maternal reasons and a delay of delivery more than 30 min may result in morbidity. Therefore, due to immediate threat to the life of the fetus or mother in those category 1 C/S, rapid anaesthesia is required. GA has been shown to provide shorter times for surgical readiness although a number of complications associated with its use and has decreased its selection for cesarean delivery in the last decades due to the widespread use of neuraxial techniques and the recognition that neuraxial anesthesia can be provided even in an urgent situations (21). For emergency caesarean section, regional anaesthesia can be chosen only when there is sufficient time to perform as the single center prospective observational study on emergency caesarean section after diagnosis of fetal distress showed (22). However, rapid sequence spinal anesthesia is a recently developed technique for the most urgent cesarean section that is category-1 Caeserean sections, where previously general anesthesia has extensively been performed. As a simulation and clinical application of rapid sequence spinal anesthesia for most urgent caesarean section stated, in terms of safety of anesthesia for C/S, spinal anesthesia is basically safer, and RSSA is designed to satisfy the time constraints of practicing RA in those urgent cases (23).

Even though the most commonly used technique is SA, there are some conditions where GA is preferred by the attending anaesthesiologist. Prospective observational study on influence of anesthesia on fetal and maternal outcome after emergency caesarean section showed varying results for neonatal outcome with SA and some with GA (24). In a situation of presumed fetal compromise, there is often pressure on the anaesthetist to perform a GA as the quickest anaesthetic option for the rapid and safe delivery of a baby. However, it is also likely to increase the risk for the mother, with a significantly higher incidence of difficult and failed tracheal intubation than the general surgical patient (25). NICE guidelines recommend that women giving birth by CS should be offered RA (if time allows) because it is safer and results in less maternal and neonatal morbidity than GA (26). Studies done in Australia on 797 term babies born by category one C/S, showed that out of 533 already compromised fetus, 81 were delivered under GA and 452 under RA (13).

GA is a classical technique when emergency caeserean section is desired to save the life of both fetus and mother in situations like fetal distress as retrospective descriptive cross-sectional study on fetal distress, options of anesthesia and immediate post-delivery outcome showed (27). This is so because it is believed to be faster regarding the required urgency and its advantage include maintained patent airway, controlled ventilation, and less cardiovascular depression (28). Use of general anesthesia also allow easier control of blood pressure and breathing and in some medical situations it may be preferable to regional such as when bleeding and clotting abnormalities are present. In patients with acute bacterial infections such as, chorioamnionitis, it is sometimes preferred to prevent infection spreading to the spinal area if regional anaesthesia is done (29).

However, GA is a leading cause of anesthetic maternal mortality which is majorly due to difficult intubation and Mendelson syndrome (a serious pneumonia) due to aspiration of gastric contents during placement of the tube (29). In the propensity score-matched analysis with 10 046 pairs, a higher incidence of severe maternal morbidity was observed among patients receiving general (2.00%) rather than neuraxial anaesthesia (0.76%). The odds ratio of severe maternal morbidity was 2.68 (95% CI, 1.97-3.64) among women receiving general compared with neuraxial anaesthesia (17). The main anesthetic considerations are the risk of aspiration of acidic gastric contents (as little as 25 ml with pH < 2.5 may lead to a 50% mortality rate) and hypoxemia resulting from airway difficulties as review article on cricoid pressure showed (30). It also affects uterine contractility especially in the use of halothane (9). The suppressive effect of anaesthetic agents on uterine muscle contraction in pregnant humans and activation of platelet receptor related to platelet aggregation might increase the risk of major haemorrhage among women undergoing Caesarean delivery under general anaesthesia (31).

Regional anesthesia is the utilization of local anesthetic solutions to induce a loss of sensation to restricted areas. Guidelines now explicitly recommend that the majority of caesarean sections should be done under regional techniques. For example, the Royal College of Anaesthetists in the United Kingdom has proposed that more than 95% of elective caesarean deliveries and more than 85% of emergency caesarean deliveries should be done using regional anaesthetic techniques (32).

Single shot spinal anesthesia is by far the most common method of anesthesia for emergency cesarean sections, and it can be as fast as general anesthesia in skilled anesthetists (33). In situations where the fetal state is compromised and delivery of the fetus must be expedited,

rapidity of spinal anesthesia could be useful. In the United Kingdom, a case series of 25 patients has described the use of spinal anesthesia in category-1 cesarean sections and reported that anesthesia can successfully be established in suitable parturients within 6-8 min with 'rapid sequence spinal' anesthesia (34).

However, in real situation for emergency cesarean sections, DDI is the main factor that affects choice of anesthesia (35). This is because the decision to delivery time interval is recommended to be less than 30 min by the RCOG as well as by the ACOG in Category 1 CS (21). Of these 30 min, 5 min are for transporting the patient to the theatre; 5 min for draping and painting, and the rest of the time for anaesthesia and delivery. As the study done in India showed, the median DDI for parturients under GA and SA were 17.5 (15- 30) and 21 (16-29.5) minutes, respectively (24). Study conducted in UK also showed that the mean DDI taken to conduct rapid sequence spinal anaesthesia for category-1 urgency caesarean section was 23 min (36). Out of 533 emergency C/S done at Mater Health Services in Australia, the decision to delivery interval (DDI) for a category one GA and SA C/S was 24.7 and 32.6 minutes, respectively (13). According to data from study done in University of Gondar, the average decision to DDI was 42 ± 21.4 min and the average time from the decision of category-1 emergency caesarean section to the operation theater arrival was 21.58 ± 19.76 min, average time from theater arrival to delivery of anesthesia was 11.5 ± 3.6 min (37). Study done in Israel also showed the mean ±SD (range) for TTI & TTD in GA and SA were 11.19 ± 10.74 (0.23–48.48) &14.15 ± 11.93 (2.00–53.02) and 19.41 ± 7.77 (0–60.9) & 25.46 ± 9.99 (1–97), respectively (38).

Study showed that there were a difference on maternal preoperative and postoperative hematocrit, intraoperative blood loss, pain perception and satisfaction (8). In contrast to regional anesthesia, general anesthesia provides a very quick and reliable start, control over the airway and ventilation and probably less hypotension (12). Regarding maternal outcomes after GA and SA study done in Israel showed that the average blood products used & ICU admissions in GA and SA were 9 (11.4%) & 5 (6.3%) and 4 (0.7%) & 1 (0.2%), respectively (38). Hypotension (MAP ≤ 20% of baseline value) was observed among 6 patients in RSSA group of 30 patients according to data from study done in India (5). Patients who had spinal anesthesia had less intraoperative blood loss compared with those who had general anesthesia (814 ± 124 vs. 842 ± 324; P = 0.0007) as the study done on comparison of Spinal versus General Anesthesia on Maternal and Neonatal Outcomes showed (39). The emergence time (512.13 ± 34.33 s with

RSGA vs. 222.10 ± 12.80 s with RSSA, P < 0.001) was much shorter with RSSA (5). According to prospective cohort study done in University of Gondar on evaluation of the decision to delivery time interval and its effect on feto-maternal outcomes and the associated factors during category-1 emergency caesarean section deliveries, out of 163 mothers who delivered with category-1 emergency C/S, 16 were transfused, 8 had lost blood which was estimated to be more than 1000 ml and 1 had died (37). Data from Jordan on comparative retrospective Study done on anesthesia for C/S among emergencies and elective stated that estimated blood loss among the emergency category was significantly higher in the general than in spinal or epidural anesthesia (40).

Comparison of fetal outcome in category one C/S under GA and SA shows that GA is associated with short-term neonatal morbidity of term babies born by category-1 CS, despite rapid delivery of the baby. Apgar score of the baby at 5 min (7.03 ± 1.99 with RSGA vs. 7.40 ± 1.83 with RSSA; P = 0.461) (5). Additionally study done in Israel showed that the number (percent) of APGAR1<7, APGAR5 <7 & transfer to NICU among GA and SA were 38 (48.1%) , 19 (24.1%) & 28 (35.4%) and 87 (15.9%), 23 (4.2%) & 122 (22.3%), respectively (38). Additionally, from the study result of Fetal distress, options of anesthesia, and immediate post-delivery outcome at state specialist hospital Akure, Nigeria, admission of neonates to the SCBU was found to be more in neonates delivered by GA than those delivered by spinal anesthesia and the relationship between type of anesthesia and SCBU admission was found to be significant P value = 0.000 (27).

Another study done at Gandhi Memorial Hospital on effects of anesthesia on APGAR and associated factors showed, out of 43 mothers, who received spinal anesthesia, 15 patients (34.88%) gave birth to neonates having Apgar score >7 at one minute and out of 43 mothers who received general anesthesia, 7(16.3%) mothers gave birth to neonate having Apgar score ≥7 at one minute (41). Retrospective comparative study on anesthesia caesarean section showed that Mean APGAR score was statistically higher in the spinal than general anesthesia among the emergency category, but there was no statistically significant difference between the anesthesia types in relation to length of stay or NICU admission between the three different anesthesia types in the emergency category (40).

Chapter 3: Objectives

3.1. General Objective

To compare general and spinal anesthesia on feto-maternal outcomes during category one cesarean deliveries at Jimma University Medical Center, 2022

3.2. Specific Objectives

1. To compare maternal outcomes between general and spinal anesthesia during category one caesarean deliveries at Jimma University Medical Center, 2022
2. To compare one and five minute Apgar scores of newborns between general and spinal anesthesia during category one caesarean deliveries at Jimma University Medical Center, 2022
3. To compare surgical and anesthesia durations between general and spinal anesthesia during category one caesarean deliveries at Jimma University Medical Center, 2022

Chapter 4: Methods and Materials

4.1 Study Area and Period

The study was conducted at Jimma University Medical Center which is located in Jimma Zone. Jimma zone is found at 352 km in the South western part from Addis Ababa, the capital city of Ethiopia. Jimma, the town of Jimma Zone, has about 120,960 total populations from which males are 60,824 (50.2%) and females are 32,191 (49.8%) according to 2007 National population and house census report (42).

JUMC is the only teaching and referral hospital in southwestern of Ethiopia. Jimma University Medical Center provide services for approximately 16,000 inpatient, 220,000 outpatient attendants, 12,000 emergency cases and 4,500 deliveries in a year coming to the hospital from the catchment population of about 15 million people. The hospital delivers health services in areas like gynecology and obstetrics, surgery, pediatrics and child health, internal medicine, ophthalmology, psychiatry, dermatology, anesthesiology and dentistry. Caeserean section is one of the surgical procedure that is mostly performed and there are two functional OR tables and 4 bedded recovery room for this purpose. The hospital has also medical, surgical and neonatal ICUs.

The study was conducted from August 20 to November 01, 2022 for two consecutive months.

4.2 Study Design

A prospective Comparative cross-sectional study was conducted at JUMC.

4.3 Population

4.3.1 Source Population

Source population were all pregnant mothers who underwent category one caeserean delivery under general and spinal anesthesia.

4.3.2 Study Population

Study population were all pregnant mothers who underwent category one caesarean delivery under general and spinal anesthesia during the study period at JUMC.

4.4 Sample Size and Sampling Technique

4.4.1 Sample Size

Sample size was computed using G-power software (version 3.1 statistical software) and the following assumptions were made: the mean of one minute Apgar score of newborn after general and spinal anesthesia from the prospective study done at Arab Republic of Egypt was 6.8±1.7 and 7.7 ±1.1, respectively (43). Confidence level of 95%, level of significance α 5%, power of the study (1-β) 80% and double population mean was used with equal allocation.

t tests - Means: Difference between two independent means (two groups)

Analysis:	A priori: Compute required sample size		
Input:	Tail(s)	=	two
	Effect size d	=	0.6285873
	α err prob	**=**	**0.05**
	Power (1-β err prob)	**=**	**0.80**
	Allocation ratio N2/N1	=	1
Output:	Noncentrality parameter δ	=	2.5143492
	Critical t	=	1.6698042
	Df	=	62
	Sample size group 1	=	32
	Sample size group 2	=	32
	Total sample size	=	**64**
	Actual power	=	0.8000791

By adding 10% for non-response rate the minimum sample size required was 72.

4.4.2 Sampling Technique

Every consecutive pregnant mothers who underwent category one caesarean section under both general and spinal anesthesia during study period was included in the sample.

4.4.3 Inclusion and Exclusion Criteria

4.4.4 Inclusion Criteria

ASA- PS II& III,

Category one emergency c/s

Singleton pregnancy,

Gestational age ≥37 weeks

4.4.5 Exclusion Criteria

Mothers with absolute contraindications for Spinal Anesthesia,
Mothers who received GA after inadequate spinal anesthesia,
Unwilling participants to consent,
Neurological impairment,

4.5 Data Collection

4.5.1 Data Collection Instruments

Data was collected by Diploma Nurses using self-developed and pretested structured questionnaires adapted from literatures. In order for assessment of maternal outcomes, data like socio-demography, obstetrics history (gravidity, parity, gestational ages and ANC visits), indication for category one caesarean section, baseline, intraoperative and postoperative vital signs (HR, SBP,DBP, MAP and oxygen saturation of peripheral arteries), blood loss, blood product transfusion, ICU admissions and death was recorded. Additionally, for assessment of newborn outcomes under general and spinal anesthesia, Apgar scores at one and five minutes, need of bag mask ventilation, intubation requirement, NICU admissions and deaths were noted. Study participants were followed until leaving from operation room table and post OR discharge area was recorded, but not followed there after.

4.5.2 Data Collection Procedure

After obtaining permission to conduct the study from Jimma University Institutional Review Board, the data collectors were trained for one day on how to fill the questionnaire prior to the start of data collection. During data collection, each participants was asked for consent and was told the objective of the study. Data was collected by asking the patient, reviewing patient chart and from anesthesia record sheet. To check for completeness of the questionnaire, a pretest study was done on 5% of sample size at JUMC and the data of those participants was not included in the final result.

4.6 Study Variables

4.6.1 Dependent variable

Primary outcome variables

Maternal blood loss

Newborn Apgar scores at 1 minute

Newborn Apgar scores at 5 minute

NICU admissions

Maternal and newborn intraoperative death

Secondary outcome variables

Postoperative ICU admissions

Need for BMV and intubation after delivery

Requirement for blood transfusion

DDI

4.6.2 Independent variables

Mode of Anesthesia

Anesthetist's experience

Experience of the obstetricians

Maternal age

BMI

Gravidity and parity

Gestational age

Fetal birth weight

Surgical and anesthesia durations

Availability of drugs

Availability of surgical materials

4.7 Operational Definitions

Intraoperative v/s: repeated record of v/s after start of anesthesia until the end of surgery

Postoperative v/s: a single record of vital signs after end of skin closure, but before patient leaving operation theatre.

Category one C/S: Is the most urgent caeserean section which needs delivery of fetus within 30 minutes of decision.

Maternal outcome: Assessed by comparing intraoperative and postoperative hemodynamic changes, blood loss, transfusion requirement, ICU admission and death under general and spinal anesthesia.

Fetal outcome: determined by comparing birth weight, one and five minute Apgar scores, NICU admission and neonatal deaths under general and spinal anesthesia.

Vital sign: is record of SBP, DBP, MAP and HR every five minutes after start of anesthesia

Baseline: value of vital signs before administration of either spinal or general anesthesia

Decision to Delivery interval: The time interval from decision to do C/S up to the delivery of the fetus.

Uterine incision to delivery time: the time taken from uterine incised to delivery of fetal head.

Persistent severe fetal bradycardia: Is sustained fetal heart rate less than 100 beats per minute.

Severe fetal tachycardia: is sustained fetal heart rate above 180 beats per minute.

Placental abruptio: Is complete or partial separation of the placenta from the decidua basalis before delivery of the fetus.

Placental previa: Is present when the placenta implants in advance of the fetal presenting part.

Cord prolapse: Occurs when the umbilical cord descends in advance of the presenting fetal part during labor.

Imminent uterine rupture: Is when there is a risk for the uterus to rupture because of active labor with previous c/s scar or from obstructed labor.

APGAR score: This variable was defined as 7-10 indicate healthy baby and 0-6 indicate distressed neonates.

4.8 Data Analysis Procedure

Data was entered to epiData 4.6 and transported to Statistical Package for the Social Sciences (IBM SPSS statistics) software version 26 for analysis. Normality of the data was checked by using Shapiro-Wilk normality test and inspected visually by histogram and Q-Q plots. Accordingly, normally distributed continuous data were analyzed using independent samples t-test to show whether there is significant difference between General and Spinal Anesthesia on Feto-maternal outcomes. Levene's test was used to test homogeneity of variances between groups. Categorical data was compared for both groups of anesthesia using Chi-Square test and presented as proportion and percentage. Significance level alpha less than 0.05 was considered to show statistically significant difference. Data was summarized and presented as texts, tables, graphs and charts.

4.9 Data Quality Assurance

The structured questionnaire was prepared in English first and translated to the local language, Afaan Oromo, and Amharic again back translation to English was made to ensure the consistency of the questionnaire. Pretest study was done on 5% of the total sample size and the data obtained from pretest study participants were not included in the final data analysis. During data collection, regular supervision and follow up was made by the assigned supervisors at the study unit. The investigator also cross checked for completeness and consistency of data on daily basis during data collection. After data collection is finished, data completeness was checked, coded and entered into epi Data version 4.6 and finally exported to IBM SPSS version 26 for analysis.

4.10 Ethical Considerations

Ethical clearance and approval to conduct this study was obtained from Jimma University Institutional review board (IRB). Informed Verbal and written consent were obtained from each study participants during contact time. The obtained data was only be used for study purpose and confidentiality and anonymity was ensured.

4.11 Dissemination Plan

Up on completion of the study, the final findings will be communicated to the concerned body and the finalized document will be submitted to anesthesia department, CBE and postgraduate office. Finally, possible efforts will be made to publish the findings on peer reviewed reputable national journal.

Chapter 5: Results

Sociodemographics of study participants between GA and SA groups at JUMC

Data were collected from 72 study participants of category one caesarean section during the study period and from this 21 cases were done under GA and 51 cases were done under SA. There was no statistically significant differences between the groups regarding sociodemographic distribution of the study participants. The mean age of patients under general and spinal anesthesia groups were 27.86± 5.42 and 26.27± 6.77 years, respectively; p = 0.344. The mean of BMI of participants under general and spinal anesthesia was 23.83± 3.38 and 22.84± 2.68 Kg/m²), respectively; p = 0.194.

Table 1: Sociodemographic characteristics of study participants under both groups

Sociodemographic		GA	SA	P_value
Age (Years)		27.86± 5.42	26.27± 6.77	0.344
BMI (Kg/m²)		23.83± 3.38	22.84± 2.68	0.194
Educational	Illiterate	2 (9.5)	17 (33.3)	0.181
	Literate	19 (90.5)	34 (66.7)	
Occupation	Gov't employee	6 (28.6)	10 (19.6)	0.669
	House wife	10 (47.6)	29 (56.9)	
	Daily labor	1 (4.8)	1 (2)	
	Merchant	4 (19)	11 (21.6)	
Residence	Urban	14 (66.7)	35 (68.6)	0.871

	Rural	7 (33.3)	16 (31.4)	
Newborn sex	Male	9 (42.9)	29 (56.9)	0.279
	Female	12 (57.1)	22 (43.1)	
Birth weight	<2.5 Kg	8 (38.1)	16 (31.4)	0.918
	2.5 – 4.0 Kg	12 (57.1)	31 (60.8)	
	>4.0 Kg	1 (4.8)	4 (7.8)	

Note: Age and BMI were presented as mean± SD and the rest as proportion (percentage)

Obstetrics history of study participants between GA and SA groups at JUMC, 2022

Concerning obstetrics history of mothers, there was no statistically significant difference between general and spinal anesthesia groups of study participants except gestational ages. The study showed that the mean gestational ages of the study participants under general and spinal anesthesia was 38.67± 1.49 and 39.55± 1.65 weeks, respectively; p= 0.038.

Table 2: Obstetrics history of category one caesarean section mothers under GA and SA

		GA N (%)	SA N (%)	P-Value
GA (weeks)*		38.67± 1.49	39.55± 1.65	0.038
	Primigravida	8 (38.1)	17 (33.3)	
Gravidity	Multigravida	10 (47.6)	24 (47.1)	0.912
	Grand-multi	3 (14.3)	10 (19.6)	
Parity	Nulliparous	12 (57.1)	16 (31.4)	
	Prim-parous	2 (9.5)	16 (31.4)	0.778
	Multiparous	7 (33.3)	18 (35.3)	
	Grand-multi	0 (0)	1 (2)	
ANC	Yes	21 (100)	49 (96.1)	0.373
	No	0 (0)	3 (3.9)	

*= Expressed as mean± SD, ANC = antenatal care

Clinical Status and indications for category one Cesarean delivery under GA and SA at JUMC, 2022

The ASA physical status distribution of the study participants were comparable between groups. Around 57.1% of study participants of general anesthesia groups were ASA_PS II while that of spinal anesthesia groups were 49%.

Category one caesarean section indications distributions under general and spinal anesthesia were statistically significantly different. Fetal bradycardia indications done under general anesthesia was 42.9% as compared to 23.5% which was done under spinal anesthesia which was statistically significantly different at p value = 0.022.

Anesthetists experience was comparable between general and spinal anesthesia groups while there was statistically significant difference between general and spinal anesthesia groups for obstetrician's experience who performed category one c/s during study period.

Table 3: Comparison indications of Category one C/S of study participants under GA and SA at JUMC, 2022

	GA N (%)	SA N (%)	P value
Cord prolapse/compression	2 (9.5)	3 (5.9)	
Abruptio placenta	1 (4.8)	3 (5.9)	
Placenta previa	4 (19)	1 (2)	
Imminent uterine rupture	2 (9.5)	13 (25.5)	
Severe bradycardia	9 (42.9)	12 (23.5)	0.022
Severe tachycardia	0 (0)	10 (19.6)	
Severe pre-eclampsia	1 (4.8)	5 (9.8)	
GIII MSAF	2 (9.5)	4 (7.8)	

MSAF: Meconium Stained Amniotic Fluid

Comparison of maternal outcomes during category one c/s between GA and SA groups

There was no significant difference between GA and SA groups of category one caesarean section patients with regards to baseline vital signs like SBP and HR. The mean baseline SBP for general and spinal anesthesia groups were 127± 18.621 and 129.12± 271 mmHg, respectively with no statistically significant difference at p value = 0.628. Additionally, the mean of baseline HR of GA and SA groups were 103.43± 14.476 and 96.24± 16.294 beats per minute, respectively; p= 0.083.

However, intraoperative maternal vital signs like SBP, DBP, MAP and HR were statistically significantly different between general and spinal anesthesia during category one caesarean sections as shown in table 4 and figure below. The overall intraoperative mean of SBP for GA and SA groups was 129.85± 13.89 and 107.25± 12.42; $p \leq 0.001$.

Table 4: comparison of SBP and HR between GA and SA during category one C/S

Time	V/S	GA	SA	p-value	(GA-SA)	95% CI
5th min	SBP	134.19± 14.600	114.94± 15.940	<0.001	19.25	11.20 – 27.30
	HR	120.24± 15.205	96.33± 15.272	<0.001	23.91	16.02 – 31.80
10th min	SBP	137.57± 23.676	109.20± 15.092	<0.001	28.38	16.92 – 39.83
	HR	118.10± 13.958	92.08± 13.198	<0.001	26.02	18.96 – 33.08
15th min	SBP	128.43± 18.557	110.06± 20.117	0.001	18.37	8.19 – 28.55
	HR	114.95± 15.445	91.92± 12.907	<0.001	23.03	15.96 – 30.11
20th min	SBP	122.43± 16.792	104.73± 20.558	0.001	17.70	7.51 – 27.89
	HR	114.76± 19.021	91.88± 14.010	<0.001	22.89	14.70 – 31.07
25th min	SBP	119.62± 12.286	103.27± 16.665	<0.001	16.35	8.26 – 24.44
	HR	116.43± 23.105	89.21± 13.738	<0.001	27.22	16.09 – 38.35
35th min	SBP	125.67±18.580	104.44± 16.893	<0.001	21.22	12.02 – 30.43
	HR	120.76± 20.964	89.27± 11.450	<0.001	31.50	21.45 – 41.54
45th min	SBP	130.81± 16.113	104.22± 12.867	<0.001	26.60	18.19 – 35.0
	HR	117.75± 17.109	88.72± 11.715	<0.001	29.03	20.84 – 37.21

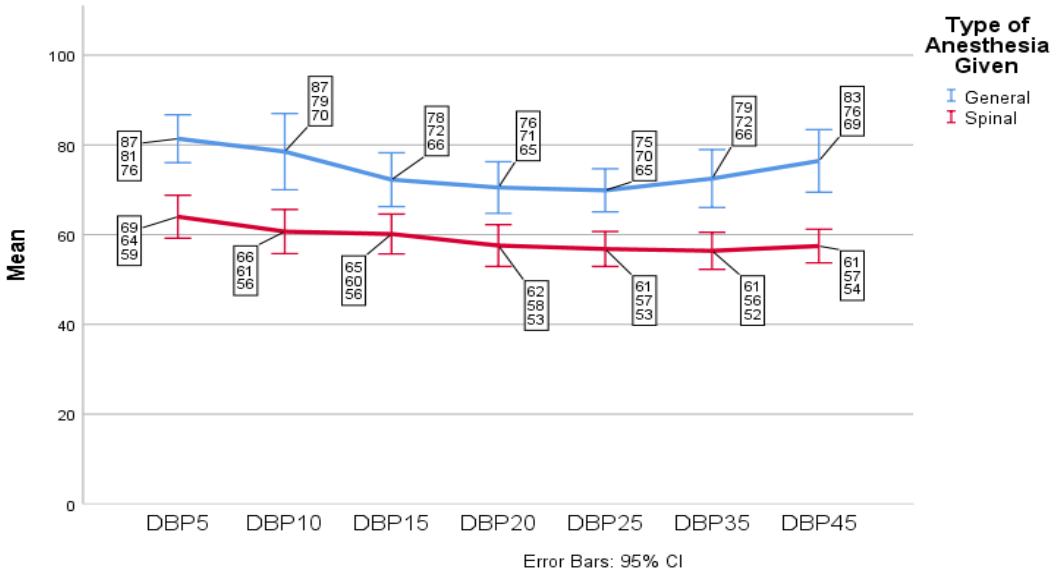

Figure 1: Line graph showing mean of intraoperative DBP at specific time for GA and SA groups of category one c/s at JUMC, 2022

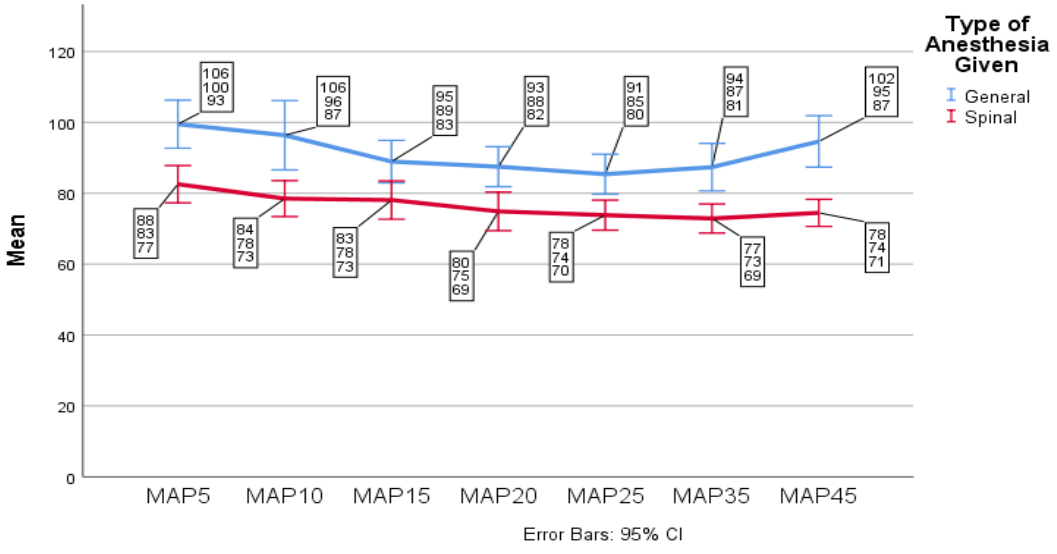

Figure 2: Line graph showing mean of intraoperative MAP at specific time for GA and SA groups of category one c/s at JUMC, 2022

Larger proportions of general anesthesia groups (42.9%) of patients lost 1000 – 1500ml of blood while only 7.8% of spinal anesthesia groups lost this much blood intraoperatively. Additionally, most patients (56.9%) of spinal anesthesia groups lost less than 500ml of blood intraoperatively and only 4.8% of general anesthesia groups lost < 500ml of blood. This shows as there is significant difference between GA and SA with regards to intraoperative blood loss with $p < 0.001$ and general anesthesia is associated with larger blood loss.

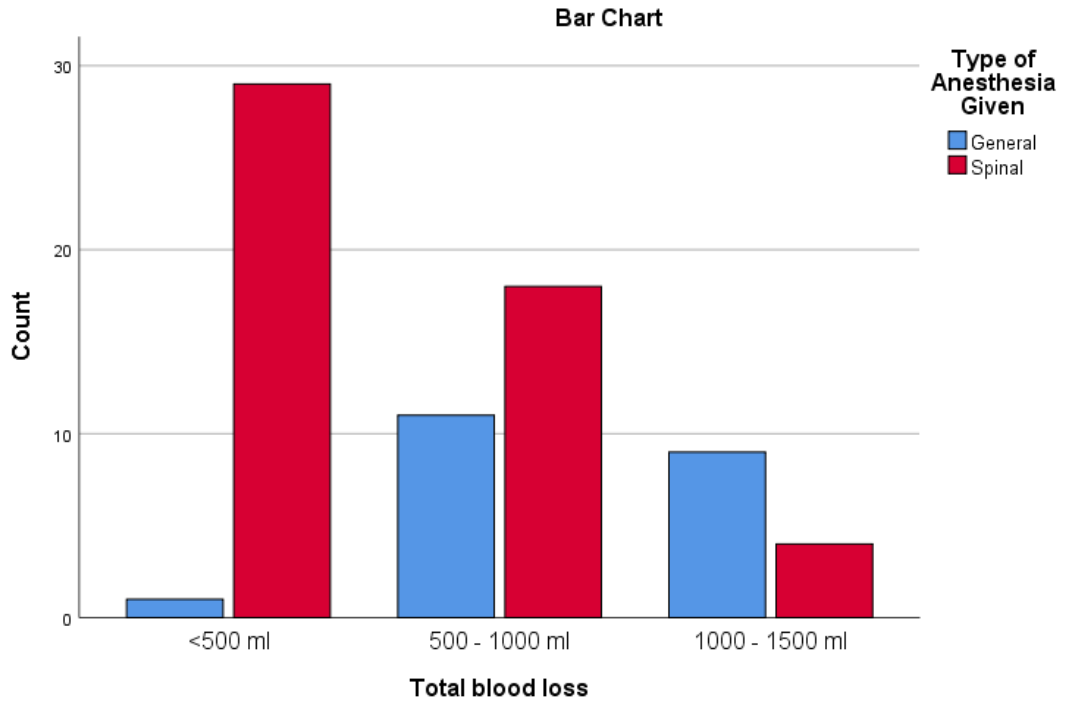

Figure 3: Bar chart showing intraoperative blood loss under both GA and SA for category one C/S patients at JUMC, 2022.

Additionally, 19% of pregnant mothers who underwent general anesthesia category one caesarean section was transfused with blood as compared to no transfusion for those who underwent delivery under spinal anesthesia with statistically significant difference at $p = 0.006$. There was no statistically significant difference between general and spinal anesthesia groups with regards to ICU admission. There were two patients admission to ICU during study period; one patient from each group. There was no maternal deaths recorded under both general and spinal anesthesia groups during study period.

Similar to the intraoperative period, the postoperative vital signs were statistically significantly different between general and spinal anesthesia groups of category one c/s. The mean of postoperative SBP and HR for general versus spinal anesthesia groups were respectively 129.43± 18.17 and 125.95± 16.53 versus 110.84± 19.16 and 89.61± 12.49, respectively; p < 0.001.

Table 5: Postoperative vital signs of study participants between GA and SA groups at JUMC, 2022

Postop vital signs	GA	SA	P-value
SBP	129.42± 18.17	110.84± 19.16	<0.001
DBP	81.52± 10.03	60.00± 10.27	<0.001
MAP	100.33± 11.94	77.02± 11.76	<0.001
HR	125.95± 16.53	89.61± 12.49	<0.001

Newborn outcomes of study participants between GA and SA at JUMC, 2022

Concerning newborn outcomes comparison under general and spinal anesthesia, the proportions of newborns with Apgar score <7 at one minute was 90.5% and 56.9% for general and spinal anesthesia groups, respectively; p= 0.006. Additionally, 61.9% of newborns delivered under general anesthesia category one caesarean sections had five minute Apgar score <7 as compared to 21.6% for those delivered under spinal anesthesia; p=0.001. This showed that there was significant difference between general and spinal anesthesia with regards to Apgar scores.

Combined assessment of newborn outcomes with requirement for BMV, intubation and NICU admissions after category one c/s under general and spinal anesthesia showed that there was statistically significant differences between groups. However, the study identified as there was no statistically significant difference between general and spinal anesthesia groups concerning newborn death. The difference could be due to small sample sizes for general anesthesia groups.

Table 6: Comparison of newborn outcome between GA and SA during category one C/S at JUMC, 2022

		GA n (%)	SA n (%)	P value
APGAR1'	<7	19 (90.5)	29 (56.9)	
	≥7	2 (9.5)	22 (43.1)	0.006
APGAR5'	<7	13 (61.9)	11 (21.6)	
	≥7	8 (38.1)	40 (78.4)	0.001
Need of BMV		15(71.4)	7 (13.7)	<0.001
Need of intubation		5 (23.8)	0 (0)	0.001
NICU admission		13 (61.9)	8 (15.7)	<0.001
Newborn death		2 (9.5)	0 (0)	0.082*

*. No statistically significant difference between GA and SA regarding newborn death. N (%) shows frequency with percentages. APGAR = Activity, Pulse, Grimace, Appearance and Respiration (All consists of points 0 – 2), BMV= bag and mask ventilation, NICU = Neonatal Intensive Care Unit.

Comparison of surgical and anesthesia durations between GA and SA groups

In association to duration of surgery and anesthesia, that there was no significant difference between GA and SA from decision to OR arrival and OR arrival to anesthesia start intervals. However, there is statistically significant difference on DDI between GA and SA groups in which median DDI among general anesthesia was nine minutes faster than that of spinal anesthesia groups [24 (20 – 35)] and [33 (28 – 42)] minutes, respectively.

Table 7: Surgery and anesthesia duration comparison between GA and SA at JUMC, 2022

	GA	SA	P value
Decision to OR entry	10 (7.5 – 14)	12 (9 – 18)	0.218*
OR entry to Anesthesia start	7 (5 – 10)	10 (6 – 14)	0.059*
Anesthesia to Skin Incision	3 (2 – 5)	5 (4 – 6)	<0.001
Skin incision to Delivery	3 (3 – 6)	5 (4 – 7)	0.025
Decision to delivery interval	24 (20 – 35)	33 (28 – 42)	0.011
Skin Closure to Pt. transfer	10 (8.5 – 14)	5 (4 – 7)	<0.001

Duration expressed as median (IQR) in minutes

Comparison of DDI ≤30 and >30 minutes and newborn outcomes

Comparison of DDI and newborn outcome showed that there was no statistically significant difference on newborn outcomes between DDI ≤30 and >30 minutes, except with regards to NICU admission. Regardless of DDI less than or equal to 30 minutes, there was larger NICU admissions of newborns as compared to when DDI being greater than 30 minutes. 41.9% of newborns delivered with DDI ≤30 were admitted to NICU while it was only 19.5% for newborns delivered with DDI >30; p= 0.038.

Table 8: Comparison of newborn outcomes between DDI ≤ 30 and > 30 minutes for category one C/S deliveries at JUMC, 2022

Newborn outcomes		DDI≤30	DDI>30	P- value
APGAR 1'	<7	24 (77.4)	24 (58.5)	
	≥7	7 (22.6)	17 (41.5)	0.092
APGAR 5'	<7	12 (38.5)	12 (29.3)	
	≥7	19 (61.3)	29 (70.7)	0.400
Need BMV		13 (41.9)	9 (22)	0.068
Need Intubation		2 (6.5)	3 (7.3)	1.00
NICU admission		13 (41.9)	8 (19.5)	0.038*
Death		0 (0)	2 (4.9)	0.503

* statistically significant differences between ≤30 and >30 minutes DDI for NICU admission

Chapter 6: Discussion

Intraoperative and postoperative maternal vital signs were significantly higher for GA groups as compared to SA. This is supported by the study done in Korea and Benha University (9,43) Both study showed intraoperative hypotension was more in spinal groups and maternal ICU admission was comparable between groups. The possible explanation for this lower values of vital signs for spinal groups could be due to spinal anesthesia effect on venous dilatation that causes venous blood pooling. Using titrated dosages of drugs and no monitoring for depth of anesthesia during general anesthesia might be the reason for higher values of vital signs for general anesthesia groups of category one c/s cases.

The study revealed that, there was larger proportions of patients with larger blood loss among general anesthesia category one c/s cases as compared to spinal anesthesia groups. Larger proportions (42.9%) of GA group of patients lost 1000 – 1500ml of blood while larger proportions (56.9%) of SA groups of patients lost less than 500ml of blood. Accordingly, the proportions of patients required blood transfusion was also higher for GA as compared to SA that is 19% versus 0%, respectively. The result of the study is comparable with the study done in Korea which stated the mean EBL under spinal anesthesia is lower than general anesthesia which is 819.9± 81.9 and 856.7± 117.9ml, respectively (9). The difference in figure for amount of blood loss could be due to estimation we used to calculate intraoperative blood loss under both groups. The explanation for larger blood loss associated with general anesthesia could be inadequate uterine contractility due to use of potent halogenated volatile anesthetics during general anesthesia. On top of this, higher blood pressure associated to general anesthesia groups could be probable cause of blood loss during general anesthesia category one c/s.

In both groups, there was no maternal death identified during study period and the proportions of ICU admission in both general 1 (4.8%) and spinal anesthesia 1 (2%) was found to be of no significant difference statistically. This is found to be supported by the study done in Italy which stated as there was no maternal and fetal deaths or major complications directly or indirectly related to anesthesia techniques (44).

Larger proportions of newborns delivered by general anesthesia had Apgar scores less than 7 at one and five minute as compared to those delivered under spinal anesthesia. Moreover, proportions of newborns delivered under general anesthesia who required mask ventilation, intubation and NICU admissions were significantly larger than those delivered under spinal

anesthesia category one caeserean sections. This finding is consistent with study done in Korea, Egypt, Australia and Italy (9,12,13,43). Another study done in Australia also supports this finding in which they showed as there were larger proportions of newborns that required bag mask ventilation, NICU admission, intubation 27.4%, 29.6%, 4.9% and 13.5%, 14.6%, 4.5%, respectively after delivery under general than after spinal anesthesia (13).

The study showed that there was significant difference between GA and SA groups regarding surgical and anesthesia durations. This study showed that the time intervals from decision to do c/s to patient OR arrival, from patient OR arrival to anesthesia start, anesthesia start to skin incision start, skin incision to delivery and over all decision to delivery interval was longer in SA groups as compared to GA groups. The DDI for GA was almost nine (9) minutes faster than that of SA in the median DDI interval for GA and SA were found to be 24 minutes and 33 minutes, respectively. This is consistent with the study done at Mater Health Services, in South Brisbane, Queensland, Australia, in which the mean of DDI in GA and SA category one C/S were 24.7 and 32.6 minutes, respectively (13). This study didn't agree with the study done in West Bengal, India, in which the time intervals for spinal anesthesia groups were lower than general anesthesia groups (36). This might be because of the professional experience, availability of necessary materials and set up design differences. In their study, they explained as the anesthesia was performed by experienced anesthesiologist. The other reason that may cause longer time interval from anesthesia start to skin incision start under spinal anesthesia is due to preparing and draping of patients after spinal anesthesia is given and additionally, local anesthetics might take longer time for onset of action as compared to general anesthetics.

Decision to delivery interval is not significantly associated to newborn outcomes, though it is recommended that it should be less than or equal to 30 minutes for category one indications by RCOG and RCoA as well as NICE (45). This study showed that there was no significant difference on newborn outcomes when DDI is >30 or ≤30 minutes. This is supported by the study done in Gondar, Ethiopia which concluded that DDI were not directly correlated to fetal outcomes (19).

The key limitation of this study is being observational study and it was conducted on small samples so further studies should consider to do more robust study design on larger enough samples.

Chapter 7: Conclusion and Recommendation

7.1 Conclusion

General anesthesia is associated with greater maternal and newborn morbidity than spinal anesthesia. Large blood loss associated to general anesthesia may be due to use of potent inhalational anesthetic agents that can cause ineffective uterine contraction. More importantly, general anesthesia causes greater newborn depression as most anesthetics crosses placental barrier and leads to newborn depression after birth as measured by combined assessment of Apgar at 1 and 5 minutes, need of bag mask ventilation, need of intubation and finally whether or not it requires NICU admission.

Additionally, general anesthesia causes increment in maternal vital signs which is not desirable during anesthesia and surgery as it leads to increased bleeding from hypertension and risks mothers for myocardial ischemia secondary to increased demand. Though spinal anesthesia is slower than general anesthesia, there is no significant maternal or fetal morbidity associated to the use of spinal anesthesia. Therefore, maximum effort should be made to choose spinal anesthesia for category one caeserean sections if there are no contraindications.

7.2 Recommendations

Every anesthetists should made maximum effort towards the selection of spinal anesthesia for category one caesarean sections if and only if he or she would complete within recommended time periods. The anesthesia department should have practice policies and guidelines for cesarean section services being done at JUMC.

Each respective stake holders should arrange necessary materials like drugs, spinal needles, local anesthetics safe for emergency cesarean section delivery services in the operation theatre.

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Annexes

Annex 1: Consent Form

Written consent form on Comparison of fetal and maternal outcomes of general and spinal anesthesia among pregnant mothers who undergo category one caeserean deliveries at JUMC, 2022

Hello!

My name is _____ I am working as a data collector for the study being conducted on Comparison of fetal and maternal outcomes of general and spinal anesthesia among pregnant mothers who undergo category one caeserean deliveries at JUMC by Bekele Bedane who is postgraduate student in clinical anesthesia at Jimma University, Faculty of Medical Sciences, and Department of Anesthesia. I kindly request you to give me your attention to explain you about the study and of being selected as study participant.

The study is intended to evaluate fetal and maternal outcomes for pregnant mothers who delivered by caeserean section as category one group under either General or Spinal anesthesia. You are selected as study participant in this study and therefore your honest and genuine participation by responding to the question is greatly needed. In case misunderstanding or ambiguity, you can ask for clarification and further understanding.

Your participation is fully voluntarily and the information you provided will completely be kept confidential. Your name will not be needed to be written on this paper and will not be used in connection with any information that you will tell us.

You have full right to discontinue from the participation if you are not interested more and no risks will happen on being participant of the study. Additionally, no financial benefits be offered for being study participant. However, being the participant of the study, you contribute for the study which will improve quality of anesthesia care for pregnant mothers who will deliver under Caeserean Section, particularly for those who are critical and at high risk of morbidity and mortality with great challenge of selecting safe anesthesia options.

Are you interested to continue? Yes_____ No_____ sign_____

Thank you very much!

I'd greatly appreciate your help in the study!

Annex 2: Questionnaire for Data Collection

Data collection instrument prepared for comparative cross-sectional study to assess the effects of General and Spinal Anesthesia on parturients who will undergo category one Caeserean Section at Jimma University Medical Center, Ethiopia 2022.

Date _____

Data collector: Name…… Profession…… Signature……

Category one C/S ☐ (if not, please do not collect data)

Maternal Card Number (MRM): _____

Data to be collected		Responses	Code
Socio-demography	Age (years)	----------	**A1**
	Educational status	1. No formal education 2. Primary school 3. Secondary school 4. College/ University	**A2**
	Occupational Status	1. Government Employee 2. House Wife 3. Daily Labor 4. Merchant	**A3**
	Place of Residence	Urban Rural	**A4**
	Weight	----------Kg	**A5**
	Height	---------- cm	**A6**
	Body mass index (BMI)	---------- Kg/m²	**A7**
Obstetrics History	Gestational age (weeks)	----------	**A8**
	Gravidity	Primigravida Multigravida Grand multipara	**A9**
	Parity	1) Nulliparous 2)Prim parous 3)Multi parous 4)Grand multiparous	**A10**
	ANC follow up	1. First visit 2. Second visit 3. Third visit 4. Fourth visit 5. No ANC follow up	**A11**
Current indication for c/s	1. Cord prolapse / compression 2. Placental abruption 3. Placental previa 4. Imminent uterine rupture 5. Severe fetal bradycardia 6. Severe pre-eclampsia 7. Imminent uterine rupture		**A12**

	8. GIII MSAF		
Maternal co-morbidity	1. Pre-eclampsia 2. Eclampsia 3. Asthma 4. DM 5. Heart disease 6. Coagulopathy (platelet count <70,000) 7. None		**A13**
Baseline maternal V/S	BP……. mmHg MAP…… mmHg HR……bpm RR…….. Bpm SPO2…… %		**A14**
Time periods	Decision for c/s time ……L.T **P**atient OR entry time…… L.T Anesthesia start time…….. ..L.T **S**kin incision start time…….. L.T Fetal delivery time…… L.T **L**ast skin closure time……..L.T Time of patient transfer from OR table to stretcher…….. L.T		**A15**
Anesthesia related	Type of anesthesia given	1.General 2.Spinal	**A16**
	Level of profession of responsible anesthetist	1.BSc 2.MSc 3.Resident 4.Anesthesiologist	**A17**
	Anesthetist	1.BSc student 2.BSc 3.MSc student 4.MSc 5.Resident 6.Anesthesiologist	**A18**
Surgery related issues	Surgeon's Experience	R2 R3 R4 Senior	**A19**
Maternal outcome data	Total blood loss	< 500ml 500 – 1000 ml 1000 – 1500 ml >1500 ml	**A20**
	Intraoperative blood transfusion	Yes No	**A21**
	Vasopressor use	Yes No	**A22**
	Oxytocin use	<10 IU >10 IU	**A23**
	ICU admission	Yes No	**A24**
	Maternal Death	Yes No	**A25**
Fetal outcome data	Birth weight	<2.5kg 2.5-4.0 kg >4.0 kg	**A26**
	APGAR 1'	<7 ≥7	**A27**
	APGAR 5'	<7 ≥7	**A28**
	Need of BMV	Yes No	**A29**
	Need intubation	Yes No	**A30**
	NICU admission	Yes No	**A31**
	Intraoperative Death	Yes No	**A32**

Intraoperative maternal vital sign format

Interval with which patient is monitored (please fill each vital signs every 5' in the first 20 min and every 10min then after until end of procedure)

V/S	5'	10'	15'	20'	25'	35'	45'	55'	1:05
	Value of monitored Vital sign at each interval time until the end of procedure								
BP (mmHg)									
MAP									
PR (bpm)									
SPO2 (%)									

DECLARATION

I, the undersigned, declare that this thesis is my original work, has not been presented for a degree in this or any other university and all sources of materials used for the thesis has been fully acknowledged.

Name: _____

Signature: _____

Name of the institution: _____

Date of submission: _____

This thesis has been submitted for examination with my approval as University advisor

Name and Signature of the first advisor_____

Name and Signature of second advisors

1. _____
2. _____