



Addis Ababa University

College of Health Sciences

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Hematological profiles of newborns from mothers with pregnancy-induced hypertension at Gandhi Memorial Hospital, Addis Ababa Ethiopia: A comparative cross-sectional study

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A research thesis submitted to the Department of Medical Laboratory Sciences, College of Health Science, Addis Ababa University, in partial fulfillment of Master of Science Degree in Medical Laboratory Sciences (Hematology and Immunohematology Specialty Track).

June 2023

Addis Ababa, Ethiopia

Addis Ababa University

School of Graduate Studies

This is to certify that the thesis prepared by Melat Mekonnen entitled: Hematological profile of newborns from mothers with pregnancy-induced hypertension at Gandhi Memorial Hospital, Addis Ababa Ethiopia and submitted in partial fulfillment of the requirements for Master of Science degree in Clinical Laboratory Sciences (Hematology and Immunohematology specialty track) complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

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Acknowledgments

First I would like to express my heartfelt gratitude to my advisors Mr. Zemen Tamir and Mr. Moges Wordofa for their constructive comments, intellectual advice and genuine guidance from the beginning to the completion of this research paper. Secondly, I am indebted to the Department of Medical Laboratory Science, College of Health Science of Addis Ababa University for providing the opportunity and financial support. I would like to extend my deepest thanks to Dawit Niku (MD, ObGyn), Midwifery professionals and medical laboratory technologists of Gandhi Memorial Hospital who had taken the full responsibility for interviewing participants, collecting cord blood and analyzing samples besides having the usual heavy workload. My sincere thanks also go to the administrative office of Gandhi Memorial Hospital for permitting and supporting this study and the study participants who had sought their time for the interview with full voluntary and support for the study. Last but not least I would like to thank my family, my husband Mr. Daniel Getacher and my friends for their support and encouragements.

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Abbreviations

Bp	Blood pressure
CBC	Complete blood count
DBP	Diastolic blood pressure
EDTA	Ethylene diamine tetra acetate
HgB	Hemoglobin
IUGR	Intrauterine growth retardation
LBW	Low birth weight
MCH	Mean cell hemoglobin
MCHC	Mean cell hemoglobin concentration
MCV	Mean cell volume
mmHg	Millimeter mercury
MPV	Mean platelet volume
NICU	Neonatal intensive care unit
nRBC	Nucleated red blood cell
PCV	Hematocrit
PDW	Platelet distribution width
PE	Preeclampsia
PIH	Pregnancy induced hypertension
RBC	Red blood cell
RDW	Red cell distribution width
SBP	Systolic blood pressure
SG	Small for gestational age
SOP	Standard operating procedure
TPC	Total platelet count
WBC	White blood cell
WHO	World health organization

Abstract

Background: Pregnancy induced hypertension is the commonest etiology for maternal and neonatal morbidity and mortality. Neonates born from hypertensive mothers are more prone to complications because of reduced oxygen supply and inadequate blood flow to the fetus. These complications include intrauterine growth retardation, prematurity, bronchopulmonary dysplasia and hematological derangements like polycythemia, neutropenia, and thrombocytopenia.

Objective: The aim of this study was to determine the hematological profiles of newborns from mothers with hypertensive disorder of pregnancy at Gandhi Memorial Hospital, Addis Ababa, Ethiopia from January –March 2023.

Methods: A comparative cross-sectional study was carried out on newborns from mothers with and without pregnancy induced hypertension. A convenient sampling technique was used to recruit 210 newborns including 70 cases and 140 controls. Cord blood sample was collected immediately after birth and the samples were analyzed using Sysmex XN 550 hematology analyzer. The obtained data was analyzed using SPSS version 20. Mann-Whitney U test were done to compare hematological profiles of the two groups. Besides, Kruskal-Wallis test were used to compare the hematological profiles of newborns from mothers with different types of hypertensive disorders. The Spearman's rank correlation was used for the correlation test. P-value < 0.05 was considered statistically significant.

Results: There was a statistically significant increase in RBC (P=0.001), HGB (P= 0.005), HCT (P<0.001), MCV (P <0.001), MCH (P=0.022), lymphocyte (P=0.044) and RDW SD (P<0.001) of cases than controls. Platelet and MCHC of newborns were significantly lower in cases than control group. Newborn RBC count and MCV were positively correlated with birth weight; platelet count was positively correlated with gestational age and negatively correlated with maternal DBP; MCH was negatively correlated with gestational week. Moreover, maternal and newborn monocyte count showed significant positive correlation whereas RBC count showed negative correlation in the case group.

Conclusion: There were significant changes in the hematological profile of newborns between hypertensive and normotensive mothers. Therefore, hematological screening of newborns of hypertensive mothers is suggested for early detection and monitoring of hematological abnormalities.

Keywords: *Hematological profile, hypertensive disorder, newborns, Gandhi, Ethiopia*

1. Introduction

1.1 Background

Pregnancy is a natural phenomenon connected with alterations in endocrine, metabolic, and anatomical processes that may have an impact on various organs and systems. In addition to helping the fetus grow and survive, these alterations are crucial for the woman to adjust to the pregnancy state. Even though most pregnancies occur without complications, more than 10 % of pregnant women experience life threatening conditions throughout their pregnancy, at birth and postpartum. The most common complications of pregnancy include high blood pressure, gestational diabetes mellitus, premature birth, miscarriage and hematological changes like physiologic anemia (due to change in plasma volume by 30–40% perhaps due to a decrease in systemic vascular resistance and increase in cardiac output), elevated neutrophil count, thrombocytopenia, increased procoagulant factors, and reduced fibrinolysis. These complications put both the mother's and fetus's health in danger(1, 2)

Hypertensive disorders of pregnancy accounts more than 15 % of pregnancy related complications and results in significant maternal and prenatal morbidity and death(3). Pregnancy induced hypertension (PIH) is an increase in diastolic blood pressure ≥ 90 mm Hg and systolic blood pressure ≥ 140 mmHg at least on two different occasions. Hypertension is said to be mild and severe when the blood pressure is $< 160/110$ mm Hg and above $160/110$ mm Hg respectively(4). Pregnancy induced hypertension based on their onset and clinical presentation are classified into four different types as; gestational hypertension, preeclampsia and eclampsia syndrome, preeclampsia superimposed on chronic hypertension and chronic hypertension(5).

Gestational hypertension is a rise in blood pressure after 20 weeks of gestation or in the first 24 hour after delivery without proteinuria or edema in a previously normotensive woman. Whereas, preeclampsia is characterized by a new onset of hypertension associated with proteinuria (> 0.3 g/dl or +1 on urine dipstick) after 20 weeks of gestation(6). As the disease progresses, additional clinical features and organ involvements like thrombocytopenia, kidney failure, liver disease and pulmonary edema maybe seen (7-9).

Preeclampsia (PE) is the most common PIH that has a worldwide prevalence of 5-8 % (6, 7). In Sub Saharan countries its prevalence ranges from 1.8- 16.7 %. Eclampsia is a rare form of hypertension which is characterized by generalized seizure or coma in preeclamptic woman (1). Superimposed preeclampsia /eclampsia is hypertension that occurs before 20 weeks of pregnancy and proteinuria is detected after 20 weeks of gestation. Different risk factors are responsible for development of pregnancy induced hypertension. These includes maternal age <20 and >35 years, primigravida, pervious history of hypertension, twin pregnancy, family history of chronic disease including hypertension and diabetes mellitus (10).

Although the pathogenesis of pregnancy induced hypertension is not fully understood, abnormal invasion of maternal wall by trophoblastic tissue at about second trimester is thought to play a crucial part in the disease progression. In normal physiology, the developing fetal allograft and the maternal tissue exhibit mutual immunologic tolerance (11) and the establishment of pregnancy during the early stages of pregnancy depends on the invasion of extra villous trophoblast into the mother's uterus. Trophoblasts are important for oxygen and nutrients exchange between the mother and the fetus. Failure of trophoblastic cells invasion result in a failure of transformation of the uterine spiral arteries and high arterial blood flow resistance which in return results in hypoperfusion and hypoxemia of the placenta. The fetus is put at risk due to uteroplacental insufficiency and vascular endothelial dysfunction caused by the inadequately perfused trophoblasts. (12).

Neonates born from mothers with hypertension are prone to intrauterine growth retardation, premature birth, bronchopulmonary dysplasia and hematological derangements like polycythemia, neutropenia and thrombocytopenia. In normal physiology, cord blood red cell, hemoglobin, hematocrit and neutrophil counts are initially high than adult values and begin to fall during neonatal life. In contrast, the platelet counts of cord blood are within the normal adult range(13). Although the exact etiology underlying for neonatal hematological derangements in pregnancy induced hypertension is unknown, the principal mechanism postulated is that maternal hypertension results in insufficient blood supply to the fetus, resulting in fetal exposure to hypoxia in the placenta. Lowered oxygen tension in placenta brings in compensatory mechanisms that lead to an elevated number of immature red blood cells and nucleated RBCs (8).

The fetal hypoxia also has a depressant effect on fetal megakaryocytopoiesis and neutrophil production. Exposure to increased level of erythropoietin consumes stem cells for production of megakaryocytic cell line which will decrease platelet production. In addition, the damaged endothelium region by vasodilation in the placenta of hypertensive mothers triggers platelet adherence to it and results in neonatal thrombocytopenia. The placental derived substances suppress natural granulocyte colony units (G-CFU) which results in decreased neutrophil count(4).

In Ethiopia, automated hematology analyzers are commonly used, and regular antenatal care follow-up includes taking blood pressure and a complete blood count. Due to its enrichment with stem cells and ease of collection, umbilical cord blood can be used for hematological, biochemical and therapeutic purposes (cord transplants) (14).

1.2 Statement of the problem

Global health and development objectives should continue to place a priority on child survival. According to world health organization (WHO) estimation, 4.3 million still births and 3.4 million neonatal deaths occur annually with 98% of the deaths were reported from developing countries(15). In 2018, more than 1.1 million neonatal deaths were reported from sub Saharan countries. The maternal education level, multiple pregnancies, inadequate ANC follow up, maternal illnesses during pregnancy, premature birth and newborn sepsis are the main causes of neonatal morbidity and mortality in sub-Saharan nations. In Ethiopia, neonatal death rate ranges between 23.4 and 44 deaths per 1000 live birth(16). In Ethiopia 67% of neonatal mortality is caused by neonatal infections and premature birth(15, 17).

Pregnancy induced hypertension plays a major role in maternal and prenatal morbidity and mortality. More than 76,000 maternal deaths are attributed to pregnancy induced hypertension and among this 66% and 20% of the deaths were reported from Sub-Saharan African and Southern Asian countries, respectively. According to studies conducted worldwide, preeclampsia and eclampsia were linked to greater rates of maternal and neonatal death as well as premature birth and small for gestational age deliveries. Compared to women who do not have hypertensive disorders of pregnancy, women with PIH have a fivefold increased risk of perinatal death.

Hypertensive disorder of pregnancy is the major causes of maternal and neonatal deaths in Ethiopia. The prevalence of PIH in Ethiopia varied from 1.2% to 18.25. The pooled prevalence of hypertension disorder of pregnancy in Ethiopia was estimated to be 6.82% (2, 18-21). Neonates born from hypertensive mothers are more likely to have hematological changes due to pro inflammatory immune response and impairment of blood cell production(6) because of reduced oxygen supply and inadequate blood flow to the fetus(3).

Neonatal thrombocytopenia occurs in as many as 22% of these infants which could result in serious, sometimes fatal intra ventricular hemorrhage in utero and after birth(22). The incidence of neutropenia is reported as high as 49% in neonate from hypertensive mothers. Severe neutropenia is directly associated with the severity of growth retardation, this could attribute to a higher risk of nosocomial infection and fatality(23).

Understanding the hematological changes during normal pregnancy may help to design a new strategy to manage pregnancy related complications. Studies conducted in developing and developed countries about the effect of PIH on hematological profiles of newborns shows inconsistent results. Although there are many studies in Ethiopia describing the prevalence pregnancy induced hypertension, no studies are conducted in assessing and comparing the hematological profiles of neonates born from hypertensive and normotensive pregnancies. There is a need to generate additional data and introduce these basic markers because CBC is the most commonly requested test overall, it will improve the clinical management of neonatal complications with no additional cost. Therefore, this study aimed to determine the hematological profiles of neonates born to mothers with maternal hypertension at Gandhi Memorial Hospital, Addis Ababa, Ethiopia.

1.3 Significance of the study

The present study was conducted to investigate the relationship between neonatal hematological profiles and maternal hypertension. This study was also aimed to compare hematological profiles of newborns from hypertensive mothers and those from normotensive mothers. This study could be helpful to suggest that neonatal hematological parameters secondary to maternal hypertension could have diagnostic and prognostic value in certain neonatal complications in early life. It also provides additional information to deepen the knowledge of health care providers for early management of neonates from hypertensive mothers and may alarm them to pay a special attention to control the development of early life complication. By doing so, this study will contribute in the reduction of pregnancy induced hypertension associated complications both in mothers and their babies, decreasing morbidity and mortality. Furthermore, the study can be used as a reference for researchers to conduct further studies.

2. Literature review

There are studies that show a significant difference in hematological profiles of neonates born from hypertensive and normotensive mothers in other countries, thus suggesting the usefulness of assessing the hematological parameters between these two groups in Ethiopia.

2.1 Change in WBC parameters

Studies conducted in Turkey(24), Iran (25), Iraq (26), India(11, 27-30) , Nigeria(31, 32), Egypt(33) , Tanzania(34) and Sudan(35) showed that white blood cell count was significantly lower in neonates born to mothers with pregnancy induced hypertension than healthy mothers. However, study conducted in India(36) showed elevated WBC count in cases than controls. No significant difference was observed in total leucocyte count between newborns of hypertensive mothers than normotensive in study conducted in Qatar (4).

According to different studies conducted in Turkey (24), Iran(25) , India(27-30, 37-39), Nigeria (31, 32) and Sudan(35, 40), the mean neutrophil count was significantly lower in newborns from hypertensive mothers than normotensive mothers. No significant difference was found between newborns from hypertensive mothers than normotensive mothers in studies conducted in Qatar(4) and Iran (26). A study in Romania revealed that maternal hypertension has an impact on the development of neonatal neutropenia and it's severity become more pronounced in neonates which are born prematurely and/or small for gestational age(41)

Studies conducted in India (28-30), Turkey(24) and Sudan (35) showed that lymphocyte counts were significantly lower in cases than controls. However study conducted in Nigeria(31) showed elevated lymphocyte counts in newborns of hypertensive mothers than normotensive mothers. Other leucocyte indices including monocyte, eosinophil and basophil counts were significantly lower in neonates of mothers with PIH as demonstrated by the study conducted in Turkey(24) and Tanzania(34).

2.2 Change in platelet parameters

Various studies conducted in Qatar(4), Turkey(24), Iran(25), Iraq(26), India (11, 27, 28, 37-39, 42, 43), Bangladesh(44), Nigeria(31, 32), Egypt(33, 45), Tanzania(34) and Sudan(35, 40) showed that the mean platelet counts in newborns of hypertensive mothers were significantly lower than neonates of normotensive mothers. In addition, the platelet count of newborns were significantly differs among cases from mothers with gestational hypertension, preeclampsia, and eclampsia (11, 42).However, the studies conducted in Turkey (24) and Nigeria(31) observed no significant differences between newborns from mothers with hypertension types in terms of platelet parameters. The mean platelet volume (MPV) and platelet distribution width (PDW) were significantly higher in study conducted in Turkey(24). However, the study conducted in Sudan found that MPV was not a significantly differ between cases and controls.

2.3 Change in RBC parameters

According to different studies conducted in Turkey (24), India(28) , Bangladesh(46) and Egypt (45), the mean RBC counts of neonates born from hypertensive mothers were significantly higher than normotensive mothers. However, a study conducted in Tanzania showed that the median RBC counts were significantly lower in cases than controls(34). No significant difference was observed in studies conducted in Iraq(26) and Nigeria(32).

The mean hemoglobin and hematocrit counts of newborns of hypertensive mothers were significantly higher in studies conducted in India(28, 29), Turkey(24) and Bangladesh(46). However, no significant difference was observed between cases and control's hemoglobin counts in studies conducted in Iraq(26) and India(27). Other finding in study conducted in Tanzania (34) showed lower hemoglobin counts in neonates born from hypertensive mothers than normotensive mothers.

Studies conducted in India(28) revealed that the mean cell volume (MCV) was significantly higher in neonates born from hypertensive mothers than normotensive mothers. Whereas, a study conducted in Iraq(26) and Tanzania(34) showed no significant difference between cases and controls. Other red cell indices (MCH & MCHC) also showed no significant difference between hypertensive and normotensive mothers.

Several studies conducted in India revealed that the reticulocyte count and nRBC were significantly increased in cases compared to controls (11, 27-29). Studies conducted in India (11), Tanzania (34) and Sudan (35) revealed that red cell distribution width (RDW) was significantly higher in newborns of hypertensive mothers than normotensive ones. Red cell abnormalities were more common among newborns of hypertensive mothers than newborns of normotensive mothers as demonstrated by the study conducted in Turkey (24).

When combined, the research discussed above offer a growing body of evidence that supports the existence of a connection between neonatal hematological profiles and maternal hypertension. There isn't a report from Ethiopia that has been published as far as my literature search goes. As a result, this study will attempt to close this gap and provide extra information to further current scientific understanding on a worldwide scale.

3. Objectives

3.1. General objectives

To determine the hematological profiles of newborns from mothers with pregnancy-induced hypertension at Gandhi Memorial Hospital, Addis Ababa Ethiopia from January- March 2023

3.2 Specific objectives

1. To compare the hematological profiles of newborns from mothers with and without pregnancy-induced hypertension at Gandhi Memorial Hospital, Addis Ababa Ethiopia
2. To correlate maternal and neonatal hematological profiles at Gandhi Memorial Hospital, Addis Ababa Ethiopia
3. To correlate the independent variables and neonatal hematological profiles at Gandhi Memorial Hospital, Addis Ababa Ethiopia

4. Hypothesis (ho)

There is no difference in hematological profiles of newborns from hypertensive mothers compared to those from normotensive mothers.

5 Methods & Materials

5.1. Study area

This study was conducted in Gandhi Memorial Hospital which is located in Kirkos- sub-city of Addis Ababa. Gandhi Memorial Hospital was laid early in 1958 and named after the well-respected Mahatma Gandhi. It is among the thirteen public hospitals under Addis Ababa Health Bureau. The hospital offers services in gynecologic, obstetric and reproductive health including family planning and sexual assault .At present; it offers outpatient, inpatient services and referral cases. The neonatal ward provides inpatient unit for more than 100 neonates each month. The labor wards are run by professional midwife nurses, health officers, neonatologists, obstetrics and gynecology specialist and consultants. The hospital daily handles 40 to 50 deliveries for mothers who come from and outside of Addis Ababa (21).

5.2. Study design and period

A comparative cross-sectional study was conducted in Gandhi Memorial Hospital, Addis Ababa, Ethiopia from January- March 2023 to determine the hematological profiles of newborns from mothers with pregnancy induced hypertension.

5.3. Population

5.3.1. Source Population

All newborns who got delivered at Gandhi Memorial Hospital were the source population.

5.3.2. Study Population

Newborns from mothers diagnosed with pregnancy induced hypertension and fulfill the inclusion criteria during the study period were included as cases and newborns from normotensive mothers that fulfill the inclusion criteria during the study period were included as control group.

5.4. Eligibility criteria

5.4.1 Inclusion Criteria

Newborns from hypertensive and normotensive pregnancies whose mothers and guardians volunteer to participate in the study were included in this study.

5.4.2. Exclusion Criteria

Newborns from mothers with risk factors like ABO and Rh incompatibility, diabetes mellitus, severe anemia, chronic hypertension, kidney and heart disease was excluded. Moreover, twin deliveries, intrauterine fetal death and those from mothers who received drugs like aspirin which cause change in hematological profile were excluded from the study.

5.5. Study variables

5.5.1. Dependent variable

- ❖
- ❖ Hematological parameters of newborns

5.5.2. Independent variables

- ❖ Types of hypertensive disorder of pregnancy
- ❖ Gestational age
- ❖ Delivery mode
- ❖ Newborn gender
- ❖ Newborn birth weight
- ❖ Parity
- ❖ Residence
- ❖ Maternal age
- ❖ Maternal blood pressure
- ❖ Previous birth complications
- ❖ Family history of chronic illness
- ❖ Maternal hematological profiles

5.6. Measurement and Data collection

5.6.1. Sample size determination

Sample size was calculated using the formula of hypothesis testing for two population means. The level of significance is set to 0.05 with Z value 1.96 and power of the test set to 80%, $\sigma =$ pooled standard deviation of the two groups $Z - \beta = 0.84$ for power of 80%

D = difference in means between two groups (m1-m2)

Since no researches were conducted in our country previously, the mean of the groups was compared using similar previous study in Macedonia that reported 21.4 and 5.3 mean and standard deviation of cases, respectively and 18.5 and 3.12 mean and standard deviation controls, respectively(36).

$$\sigma^2 = (S1^2 + S2^2)/2$$

$$\sigma^2 = (5.32 + 3.122)/2 = (28.09 + 9.7344)/2 = 18.9122$$

$$n = \frac{2\sigma^2 (1.96 + Z_{-\beta})^2}{D^2}$$

$$n = 2 * 18.9122 (1.96 + 0.84)^2 / (21.4 - 18.5)^2$$

$$n = 37.8244 * 7.84 / 8.41$$

$$n = 35 \text{ with } 15\% \text{ non-response rate} = 40$$

So, the sample size required for cases (hypertensive mother and neonates) was 40. To increase the accuracy of the result, the number of controls (normotensive mothers and neonates born from normotensive women) were doubled. The sample required for control, $n_2 = 2(n_1) = 80$

$$N = n_1 + n_2 = 40 + 80; N = 120$$

The minimum sample size taken was 120, thus, the study included 70 newborns from hypertensive mothers and 140 controls; a total 210 study participants were included in this study.

5.6.2. Sampling technique

Convenient sampling technique was used by which individuals who fulfill the criteria were recruited consecutively.

5.6.3. Data collection procedure

All the personnel participated in data collection received training. The training covered the purpose of the research, how study participants should be chosen, data confidentiality, safety, and the precautions that should be taken in cord blood collection, transportation, analysis and storage. Socio-demographic and maternal clinical information was collected using pretested questionnaire and checklists through interview by assigned Midwives. A blood pressure cuff was

applied on the left arm of the mothers and the stethoscope was placed at the site of brachial artery for blood pressure measurement. Then the inflation and deflation of pulse was noted. It was measured two times and the mean value was used. About 2 ml of cord blood sample was collected immediately after birth aseptically from all the study participants by clamping and cutting the cord in between the clamps, then inserting the syringe at the placental end of the cord and collecting about 2 mL of cord blood into EDTA tube. Then cord blood was analyzed for hematological parameters using sysmex XN550 hematological analyzer. Soon after cord blood collection, the newborn was placed on weight scale. When the scale stops moving, the weight of the newborn was noted and recorded. Maternal hematological profile before delivery was taken from their record.

5.6.4 Hematological analysis

The Sysmex XN-550 is multi-parameter quantitative automated hematology analyzer for in vitro diagnostic use in determining whole blood diagnostic parameters. The devices perform hematology analyses based on the hydrodynamically focused impedance measurement, the flow cytometry method (using a semiconductor laser) and the SLS-hemoglobin method. The impedance technology is based on the principle that an electrical field, created between two electrodes of opposite charge, can be used to count and determine the size of cells. Blood cells are poor conductors of electricity. The diluent in which they are suspended as they pass through the aperture during counting is an isotonic solution which is a good conductor of electricity. Consequently, when the cells suspended in the diluent pass through the aperture between the electrodes, each individual cell will momentarily increase the impedance (resistance) of the electrical path between the electrodes. Each cell generates an electrical pulse; in proportion to its size. The device counts and sizes red blood cells (RBC) and platelets (PLT) using hydrodynamic impedance counting (sheath flow DC method). At the same time the hematocrit (HCT) is measured as a ratio of the total RBC volume to whole blood via the RBC pulse height detection method. Flow cytometry is a method used to analyze those cells and particles as they pass through extremely small flow cells with light beam. The angle of light scattered when striking a cell depicts cell size and/or yields information about cellular characteristics: cell size and granularity.

5.7. Quality Assurance

The cord blood samples were collected, prepared, and tested in accordance to standard operating procedure (SOP) to get a reliable result from the study. The samples were checked whether they are hemolyzed, clotted, sufficient volume, properly labeled and its collection time. Before the analysis, samples were inverted 10-15 times. The quality of Sysmex XN 550 was checked by commercially prepared cell quality control reagents. The result of complete blood counts was registered as the exact number (value) on standardized recording format.

5.8. Data analysis and interpretation

Prior to analysis, data were reviewed for consistency and completeness. The obtained data was analyzed using the Statistical Package for Social Sciences (SPSS) software (version 20). The results were presented using tables. Also, the descriptive statistics such as percentage, mean, median, interquartile range (IQR), and standard deviation (SD) were calculated. The data was checked for normality by the Shapiro-Wilk test. Mann-Whitney U test were used for comparison of hematological profiles between study and controls groups while Chi-square was used, to compare qualitative parameters between the groups. Additionally, a Kruskal-Wallis test for skewed data was used for the comparison of hematological profiles of newborns from mothers with different types of PIH. A Bonferroni post hoc test was used to identify the hematological profiles of newborns between different types of PIH that showed significant differences. Spearman's rank correlation was used to test the correlation between the hematological profiles of newborns and independent variables. The P-value < 0.05 was considered statistically significant

5.9. Ethical considerations

Ethical approval was obtained from Addis Ababa University, College of Health Science, Department of Medical Laboratory Science research and ethical review committee (DRERC). Ethical clearance was also obtained from Addis Ababa public health research and emergency management and Gandhi memorial hospital administration office and concerned bodies was communicated and permission was given. Informed consent/ assent was obtained from the caregivers or parents of the newborns and the study's purpose, risks, benefits and right to discontinue from the study was described for the study participants. Samples were labeled and confidentiality of participant's data was maintained throughout the study. Abnormal

hematological profile of neonates was communicated with responsible healthcare workers in the hospital for appropriate interventions.

5.10. Dissemination of the result

The result of this study will be submitted and presented to Addis Ababa University, College of Health Science, Department Medical Laboratory and to Gandhi memorial hospital. Furthermore, the study findings will be sent to the publisher in the international or local peer-reviewed journals to access the information for students, health workers, researchers, policymakers, and anyone interested in the subject area.

5.11 operational definitions

Hypertensive: A rise in Diastolic blood pressure ≥ 90 mmHg and systolic blood pressure ≥ 140 mmHg or both in two separate occasions; or a single blood pressure recording of $\geq 160/110$ mmHg.

Normotensive: A rise diastolic blood pressure ≤ 90 mmHg and systolic blood pressure ≤ 140 mmHg, or both in two separate occasions

Proteinuria: measurements of urine protein dipstick of at least 1+ (30 mg per dL), ≥ 300 mg of protein in a 24-hour urine sample; or a urinary protein/creatinine ratio of 0.3 or greater.

Intrauterine growth restriction (IUGR): reduced fetal growth in the uterus during pregnancy.

Low birth weight: weight of newborn less than 2.5 kilo grams (5.5 pounds).

Neonatal thrombocytopenia: - a platelet count $< 132.7/\mu\text{L}$ (14).

Neonatal neutropenia: - neutrophil count $< 1500/\text{mm}^3$ in the first 3 days of life (14)

Neonatal polycythemia: The level of hematocrit is greater than 58.1% (14)

Study Design Flow Chart

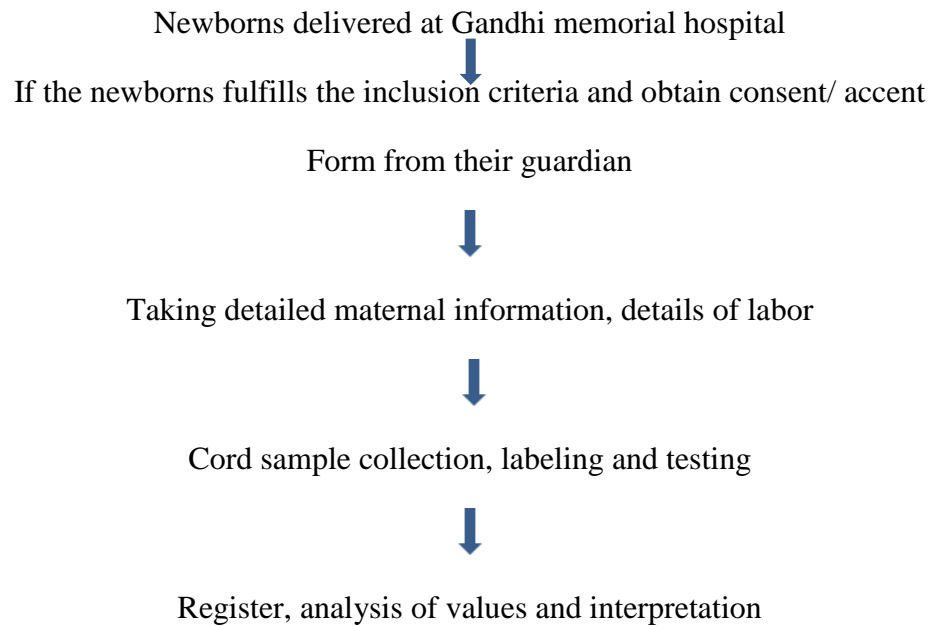


Figure1. Study design flow chart

Variables		Hypertensive N (%)	Normotensive N (%)	COR 95% CI	P value	AOR 95% CI	P value
Age of the mother							
	<20 years	2(2.9)	4(2.9)	2.00(0.08-51.59)	0.676	3.28 (0.08-128.55)	0.525
	20-30 years	50(71.4)	111(79.3)	2.22 (0.14-36.21)	.576	2.85(0.12-67.38)	0.516
	31-40 years	17(24.3)	24(17.1)	1.412 (.082-24.178)	0.812	1.87 (0.077-45.49)	0.701
	>40 years	1(1.4)	1(0.7)	1		1	1
Residence of the mother							
	Urban	35(50)	102(72.9)	2.684 (1.475-4.884)	0.001	3.04(1.55-5.96)	0.001
	Rural	35(50)	38(27.1)	1		1	1
Educational background of the mothers							
	Illiterate	2(2.8)	10(7.1)	3.33 (0.66-16.85)	0.145	4.01(0.69-23.41)	0.123
	Primary	27(38.5)	53 (37.9)	1.429(.495-4.126)	0.510	2.37(0.70-8.02)	0.166
	Secondary school	21(30.2)	47(33.6)	1.267 (.579-2.772)	0.554	1.16 (0.47-2.82)	0.750
	Collage and above	20(28.5)	30(21.4)	1		1	1
Parity							
	Primigravida	27(38.6)	66(47.1)	1.420 (.792-2.549)	0.239	1.06 (0.55-2.06)	0.857
	Multigravida	43(61.4)	74(52.9)	1			

Current delivery mode								
	SVD	32(45.7)	99(70.7)	2.87 (1.58-5.20)	0.001	2.73(1.42-5.23)	0.003	
	CS	38(54.3)	41(29.3)	1		1	1	
Sex of the newborn								
	Female	39(55.7)	73(52.1)	1.37 (0.77-2.44)	0.284	1.38 (0.74-2.58)	0.317	
	Male	31(44.3)	67(47.6)	1				
Mean SBP of mothers		145±9.3	114±8.57					
Mean DBP of mothers		93.9±7.52	72.2±7.3					
Mean Gestational week		37.7±2.3	39.9±1.74					
Mean weight of newborn(kg)		2.49±0.49	2.97±0.34					

6. Results

6.1 Socio-demographic and obstetrics characteristics of study participants

Two hundred ten newborns and their mothers were enrolled in this study, of which 70 of them were deliveries complicated with hypertension whereas the rest 140 were normotensive deliveries. Majority of the respondents aged between 20-30 years. About 55% (117) of the mothers were multigravida. Cesarean section was the commonest delivery mode for hypertensive mothers (54.3%) compared with normotensive mothers (29.3%) and the difference was statistically significant (<0.001). Previous pregnancy complication was seen in 9% and 3% of hypertensive and normotensive mothers respectively and the difference was statistically significant (<0.001). The mean SBP of hypertensive mothers was 145 ± 9.3 mmHg, while normotensive mothers had 114 ± 8.57 mmHg. The mean gestational week for hypertensive deliveries were 37.7 ± 2.3 and 39.9 ± 1.74 for normotensive deliveries and the difference was statistically significant (<0.001) (Table 1).

Table1. Socio demographic and obstetrics characteristics of mothers with and without hypertensive disorder of pregnancy at Gandhi memorial hospital, Addis Ababa from January-March 2023 (n=210)

Variables		Hypertensive N (%)	Normotensive N (%)	COR 95% CI)	P value	AOR 95% CI)	P value
Age of the mother							
	<20 years	2(2.9)	4(2.9)	2.00 (0.08- 51.59)	0.676	3.28 (0.08-128.55)	0.525
	20-30 years	50(71.4)	111(79.3)	2.22(0.14-36.21)	0.576	2.85(0.12- 67.38)	0.516
	31-40 years	17(24.3)	24(17.1)	1.41(0.08-24.18)	0.812	1.87(0.08- 45.49)	0.701
	>40 years	1(1.4)	1(0.7)	1		1	1
Residence							
	Urban	35(50)	102(72.9)	2.684 (1.475- 4.884)	0.001	3.04(1.55- 5.96)	0.001*
	Rural	35(50)	38(27.1)	1		1	1

Mothers educational background							
	Illiterate	2(2.8)	10(7.1)	3.33(0.66-16.85)	0.145	4.01(0.69- 23.41)	0.123
	Primary	27(38.5)	53 (37.9)	1.429(.495- 4.126)	0.510	2.37(0.70- 8.02)	0.166
	Secondary school	21(30.2)	47(33.6)	1.267 (.579- 2.772)	0.554	1.16 (0.47- 2.82)	0.750
	Collage and above	20(28.5)	30(21.4)	1		1	1
Parity							
	Primigravida	27(38.6)	66(47.1)	1.42 (0.79-2.55)	0.239	1.06 (0.55- 2.06)	0.857
	Multigravida	43(61.4)	74(52.9)	1	1	1	1
Current delivery mode							
	SVD	32(45.7)	99(70.7)	2.87 (1.58- 5.20)	0.001	2.73(1.42- 5.23)	0.003*
	CS	38(54.3)	41(29.3)	1	1	1	1
Sex of the newborn							
	Female	39(55.7)	73(52.1)	1.37 (0.77- 2.44)	0.284	1.38 (0.74- 2.58)	0.317
	Male	31(44.3)	67(47.6)	1	1	1	1
Mean SBP of mothers		145±9.3	114±8.57				
Mean DBP of mothers		93.9±7.52	72.2±7.3				
Mean Gestational week		37.7±2.3	39.9±1.74				
Mean weight of newborn(kg)		2.49±0.49	2.97±0.34				

Note: CS: Caesarians section, SVD: Spontaneous vaginal delivery, DBP: diastolic blood pressure, SBP: systolic blood pressure, * indicates statistically significant at p-value <0.05.

6.2 Hematological profiles of newborns and their mothers

The median± IQR WBC counts of newborns were 13.86±6.18 and 14.15±6.31 for case and control groups, respectively. The median platelet count for newborns in case groups were 179.5±122.5 and 279.5±111.2 for control groups. There was a statistically significant increase in RBC (P=0.001), HGB (P= 0.005), HCT (P=<0.001), MCV (P=<0.001), MCH (P=0.022), lymphocyte (P=0.044) and RDW SD (P=<0.001) of newborns of hypertensive mothers than normotensive ones. In contrast, the median platelet counts of newborn (P=0.001), MCHC (P=0.022) and platelet of mother (P=0.001) were significantly lower in cases compared to control group. No significant difference was seen in the median neutrophil, eosinophil, basophil, monocyte, MPV count between the case and control group. (Table 2)

Table 2 Hematological profiles of newborns and their mothers with and without hypertensive disorder of pregnancy at Gandhi memorial hospital, Addis Ababa from January- March 2023 (n=210)

CBC parameter	Newborn			Mother		
	Hypertensive median ±IQR	Normotensive median ±IQR	P-value	Hypertensive median ±IQR	Normotensive median ±IQR	P-value
WBC(x10 ³ /L)	13.86±6.18	14.15±6.31	0.321	10.63±4.41	10.65±.1	0.740
RBC(x10 ⁶ /L)	4.42±0.7	4.2±0.77	0.001*	4.05±0.8	3.97±.65	0.604
HgB(g/dL)	16.2±2.28	15.4±2.87	0.005*	12.45±1.96	12.7±1.78	0.397
HCT (%)	49.3±6.8	46.3±8.6	<0.001*	35.5±5.70	36±5.13	0.178
MCV(fl)	113.2±7	110.3±7.07	<0.001*	88.5±7.82	89.5±6.95	0.191
MCH(pg)	37.1±1.97	36.6±2.3	0.022*	31.7±2.45	32±2.73	0.518
MPV(fl)	9.7±1.50	9.75±1.0	0.987	10.4±1.78	10.6±1.70	0.950
MCHC(g/dL)	32.7±1.75	33.2±1.10	0.022*	35.4±1.60	35.5±1.70	0.657
PLT(x10 ³ /L)	179.5±122.5	279.5±111.2	<0.001*	202±75.5	229±103.2	0.001*
Neu %	52.6±12.4	55.8±14.88	0.111	74.7±12.95	72.5±14.2	0.398
Lym%	36.3±15.6	32.15±15.5	0.044*	18.2±10.4	18.5±13.6	0.413
Mon %	8.5±2.55	8.4±3.17	0.500	6.3±2.5	5.8±2.35	0.293
Eos %	1.2±1.50	1.5±1.38	0.177	0.6±1.22	0.6±1.2	0.840
Baso %	0.4±0.22	0.4±0.2	0.266	0.2±0.23	0.3±0.1	0.304

RDW SD(fl)	73.3±12.15	69.2±8.8	<0.001*	44.7±7.31	44.7±7.68	0.773
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Note: WBC: white blood cell, RBC: Red blood cell, Hgb: Hemoglobin, MCV: Mean cell volume, MCHC: Mean cell hemoglobin concentration, MCH: Mean cell hemoglobin, RDW: Red cell distribution width, MPV: Mean platelet volume, Neu: neutrophil, Lym: lymphocyte, Mon: monocyte Eos: eosinophil, Baso: basophil fl: femto liter, pg: pictogram,

NB: * indicates statistically significant at p-value <0.05.

6.3.1 Hematological profiles of newborns from different HDP types

Gestational hypertension was the commonest hypertension type among cases (48.6%), followed by preeclampsia (32.9%) and superimposed preeclampsia (18.5%). The median platelet count of newborns from mothers with preeclampsia was 129.5±99 while, it was 221.5±146 in newborns from mothers with gestational hypertension (P=0.034). The median MPV count of newborns from mothers with superimposed preeclampsia and preeclampsia was 9.10±2.75 and 10±1.2 respectively (P=0.037). (Table 3)

Table 3 Hematological profiles of newborns from different types of HDP at Gandhi memorial hospital, Addis Ababa from January- March 2023 (n=70)

CBC parameter	Gestational hypertension (median ±IQR)	Preeclampsia (median ±IQR)	Superimposed preeclampsia (median ±IQR)	P-value
WBC	13.87±4.70	13.93±7.39	12.4±5.36	0.237
RBC	4.46±0.63	4.55±0.64	4.31±0.84	0.142
HgB	16.5±2.75	16.3±2.90	16±2.95	0.312
HCT	49.61±6.88	49.7±6.90	49.2±7.05	0.180
MCV	111.8±6.6	114±10.3	115.5±8.7	0.112
MCH	37±2.37	37.1±1.8	36.8±2.90	0.520
MPV	9.75±1.53	10±1.2	9.10±2.75	0.037*
MCHC	32.9±1.55	32.5±1.5	32.5±2.56	0.972
PLT	221.5±146	129.5±99	197±95	0.034*
Neutrophil	50.1±12.5	56.8±16.2	49.6±19.9	0.188
Monocyte	8.4±1.75	9±3.9	8.1±3.6	0.227

Lymphocyte	38.5±12.1	30.7±15.1	39.4±20.1	0.539
Eosinophil	1.45±1.38	1±1.90	1±1.2	0.166
Basophil	0.45±0.25	0.4±0.3	0.4±0.35	0.963
RDW SD	72.5±10.33	73.9±13.1	74.3±12.1	0.588

NB: * indicates statistically significant at p-value <0.05.

6.3.2 Hematological profiles of mothers from different HDP types

The median MCHC count of mothers with gestational hypertension were 35.5±1.57 while it was 35.8±1.1 in superimposed preeclampsia (p= 0.048). (Table 4)

Table 4 Hematological profiles of mothers from different types of PIH at Gandhi memorial hospital, Addis Ababa from January- March 2023 (n=70)

CBC parameter	Gestational hypertension (median ±IQR)	Preeclampsia (median ±IQR)	Superimposed preeclampsia (median ±IQR)	P-value
WBC	9.84±3.62	10.9±5.02	12.02±5.93	0.120
RBC	4.16±0.73	3.91±0.74	3.86±1.10	0.203
HgB	12.6±1.83	12.5±3.2	12.1±2.85	0.430
HCT	35.9±4.8	35.5±9.1	35.6±10.4	0.517
MCV	88±9.35	89±4.7	88.6±8.35	0.689
MCH	31.5±2.98	31.8±2	32.7±2.65	0.282
MPV	10.9±1.95	10.1±1.5	10.3±1.3	0.152
MCHC	35.5±1.57	35.2±1.6	35.8±1.1	0.048*
PLT	198.5±68.2	198±73	225±95	0.600
Neutrophil	72.3±12.4	74.9±14.7	76.6±12.4	0.693
Monocyte	5.75±2.4	6.8±2.8	6.7±2.9	0.952
Lymphocyte	19.7±9.5	17.9±13.3	14.8±11.6	0.445
Eosinophil	0.6±1.4	0.2±0.9	0.9±1.1	0.192
Basophil	0.2±0.2	0.1±0.1	0.2±0.15	0.777
RDW SD	45.1±7.3	44.6±5.6	42.4±9.7	0.129

NB: * indicates statistically significant at p-value <0.05.

6.4 Post hoc test for platelet count, MPV of newborns and MCHC of mothers with different types of HDP

Post hoc test analysis showed that platelet counts significantly differ between newborns from mothers with gestational hypertension and those with preeclampsia ($P = 0.025$). There was no significant difference in MPV and MCHC counts of newborns and mothers with regard to hypertension type. (Table 5)

Table 5 Post hoc analysis for platelet count, MPV of newborns and MCHC of mothers with different types of PIH at Gandhi memorial hospital, Addis Ababa from January- March 2023 (n=70)

CBC parameter	Types of PIH	Gestational hypertension (P value)	Preeclampsia (P value)	Superimposed (P value)
MPV of newborn	Gestational	1.000	1.000	1.000
	Preeclampsia	1.000	1.000	1.000
	Superimposed preeclampsia	1.000	1.000	1.000
Platelet of newborn	Gestational	1.000	0.025*	1.000
	Preeclampsia	0.025*	1.000	1.000
	Superimposed preeclampsia	1.000	1.000	1.000
MCHC of mothers	Gestational	1.000	1.000	1.000
	Preeclampsia	1.000	1.000	1.000
	Superimposed preeclampsia	1.000	1.000	1.000

NB: * indicates statistically significant at p-value < 0.05 .

6.5 Correlations of hematological profiles of newborns with independent variables

Platelet counts of newborn had a significant positive correlation with maternal DBP ($P=0.019$), while the other parameters didn't show a significant correlation with maternal blood pressure. RBC and MCV counts of newborns showed a significant positive correlation with weight of newborn ($P=0.044$ and $P=0.020$ respectively). In contrast, MCH counts were negatively correlated with weight of the newborn ($P=0.019$). Platelet count had a significant positive

correlation with gestational week (P=0.014), while MCH had a negative correlation (P=0.004).RBC counts of newborns were negatively correlated with RBC counts of the mother (P=0.040), while Monocyte counts of newborns had positive correlation with maternal monocyte count (P=0.050). (Table 6), (Table 7)

Table 6 Correlation of independent variables with hematological parameters of newborns of hypertensive mothers at Gandhi memorial hospital, Addis Ababa from January- March 2023 (n=70)

CBC parameter	DBP(P-value)	SBP(P-value)	Weight of newborn(P-value)	Gestational week(P-value)
WBC ^{rho}	0.041(.738)	-0.071(.559)	-0.060(.619)	-0.118(.331)
RBC ^{rho}	-0.010(.934)	-0.136(.262)	0.242(.044)*	-0.136(.260)
HgB ^{rho}	-0.036(.768)	-0.014(.910)	0.186(.124)	-0.166(.170)
HCT ^{rho}	-0.048(.691)	-0.062(.608)	0.185(.126)	-0.125(.302)
MCV ^{rho}	0.205(.089)	-0.050(.681)	0.278(.020)*	0.170(.158)
MCH ^{rho}	0.093(.446)	0.030(.806)	-0.280(.019)*	-0.341(.004)*
MPV ^{rho}	-0.067(.583)	-0.118(.333)	0.024(.844)	-0.072(.555)
MCHC ^{rho}	0.020(.871)	-0.039(.751)	0.041(.737)	-0.178(.141)
PLT ^{rho}	-0.183(.019)*	-0.097(.426)	0.209(.082)	0.292(.014)*
Neutrophil ^{rho}	-0.088(.467)	-0.178(.141)	0.078(.520)	0.047(.701)
Monocyte ^{rho}	0.077(.528)	0.129(.288)	-0.083(.495)	-0.47(.70)
Lymphocyte ^{rho}	-0.014(.911)	0.037(.758)	-0.074(.545)	0.025(.839)
Eosinophil ^{rho}	-0.020(.869)	0.068(.577)	0.222(.065)	0.202(.093)
Basophil ^{rho}	-0.022(.858)	0.140(.249)	0.133(.272)	0.207(.085)
RDW SD ^{rho}	.190(.115)	0.073(.551)	-0.224(.062)	-0.117(.335)

NB: * indicates statistically significant at p-value <0.05, rho= Spearman's rank correlation

Table 7 Correlation of hypertensive mothers hematological parameter with hematological parameters of newborns at Gandhi memorial hospital, Addis Ababa from January- March 2023 (n=210)

CBC parameter Newborn- mother	Study group (P- value)	Control group (P- value)
WBC(N)- WBC(M) ^{rho}	0.175(.148)	0.051(.550)
RBC(N)- RBC(M) ^{rho}	-0.226(.040)*	0.155(.068)
HGB(N)- HGB(M) ^{rho}	0.010(.931)	0.253(.003)*
HCT(N)- HCT(M) ^{rho}	-0.055(.649)	0.134(.113)
MCV(N)- MCV(M) ^{rho}	0.097(.423)	0.004(.961)
MCH(N)- MCH(M) ^{rho}	-0.122(.315)	0.008(.930)
MPV(N)- MPV(M) ^{rho}	0.004(.915)	0.112(.189)
MCHC(N)- MCHC(M) ^{rho}	0.086(.478)	0.002(.978)
PLT(N)- PLT(M) ^{rho}	0.118(.131)	0.111(.193)
Neutrophil (N)- Neutrophil(M) ^{rho}	-0.186(.124)	0.174(.040)*
Monocyte (N)- Monocyte(M) ^{rho}	0.234(.040)*	0.202(.017)*
Lymphocyte(N)- lymphocyte(M) ^{rho})	-0.146(.228)	0.125(.142)
Eosinophil (N)- Eosinophil (M) ^{rho}	0.007(.954)	0.088(.299)
Basophil(N)- Basophil(M) ^{rho}	0.103(.397)	0.225(.008)*
RDW SD(N)- RDW SD(M) ^{rho}	-0.076(.533)	0.048(.578)

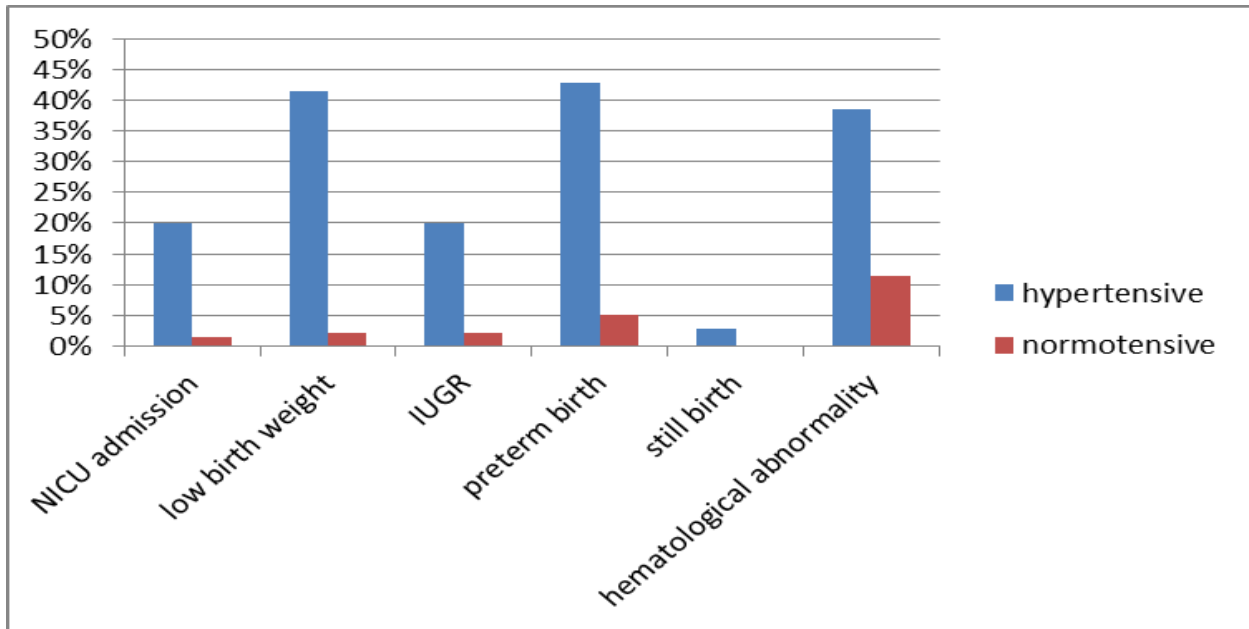
NB: * indicates statistically significant at p-value <0.05, rho= Spearman's rank correlation
N= newborn, M= mother

6.6 Neonatal outcome among study participant

During the study period, 20% newborns of hypertensive mothers were admitted to NICU. 42.9 % and 41.4% newborns of hypertensive mothers were prematurely delivered and had low birth

weight respectively. The incidence of thrombocytopenia and polycythemia in study group were 32.9% and 5.7% respectively while it was 9.3% and 2.1% in control group. (Table 8)

Figure2. Newborn outcomes delivered from mothers with and without hypertensive disorder of pregnancy at Gandhi memorial hospital, Addis Ababa from January- March 2023 (n=210)



7. Discussion

Pregnancy induced hypertension is one of the principal cause of maternal and neonatal morbidity and mortality in sub Saharan Africa countries (18). These disorders are associated with adverse neonatal complications including intrauterine growth retardation, broncho pulmonary dysplasia, fetal demise and hematological derangements(4). Thus, this study was aimed to assess hematological profiles of newborns of mothers with hypertensive disorders of pregnancy.

In this study, the frequency of cesarean section among hypertensive mothers was higher than normotensive mothers. The probable reason for this is that pregnancy induced hypertension is known to cause fetal distress syndrome which is the commonest indication for cesarean section (47). In our study, the mean weights of newborns of hypertensive mothers were significantly lower and the incidences of low birth weight among cases were higher than that of control groups. This finding is similar to studies conducted in Palestine(48), Iraq(26), India(37)and Ethiopia(49). This is due to poor placental perfusion secondary to maternal hypertension resulting in compromised blood flow to fetus. Inadequate blood flow could result in intrauterine growth retardation and later low birth weight of the newborn(3). Another reason is due to early delivery to halt the disease progression which could result in prematurity(50).

In the current study, the mean gestational week of delivery in hypertensive mothers were lower compared to normotensive mothers. This may be attributed to the need to resolve severe hypertension cases by inducing premature delivery. In addition, the incidences of neonatal intensive care unit admission among cases were higher than that of control groups. This was due to an increase in number of premature deliveries, the need for resuscitation and low birth weight among newborns of hypertensive mothers than normotensive mothers(40).

In the present study, the median WBC counts showed no significant difference between study and control groups. The finding is similar to the studies conducted in Qatar (4), India (29), and Nigeria(31, 32). In contrast to our findings, there was a significant difference in WBC counts between newborns of hypertensive and normotensive groups in studies conducted in India(11, 27, 37, 39), Turkey(24) and Iraq(26).moreover, all differential counts except for lymphocyte didn't show any significant difference between study and control groups. The probable reason for elevated lymphocyte count might indicate an imbalance in immune cells of newborns of hypertensive mothers. This finding is consistent with previous studies conducted in Qatar(4),

Iraq (26) and India (39). In contrast to our finding; there was a significant difference in differential counts between newborns of hypertensive and normotensive groups in studies conducted in India (11, 37, 42, 43), Turkey(24) and Tanzania(34). The possible reason for the result variation of WBC and differential count in this study compared to others may be due to the difference in genetics, environmental factors, ethnicity, nutritional status and sample size of the study.

In the current study, the median RBC counts were significantly higher among cases. This finding is consistent with previous studies conducted in Turkey(24), India(28) and Egypt(33). However it contradicts with studies conducted in Tanzania(34) and Sudan(35) where RBC count of cases were significantly lower than controls. Furthermore, the median hemoglobin counts were significantly higher among newborns of hypertensive mothers compared to normotensive mothers. The current findings were similar to studies conducted in India(28, 29), Turkey(24), Nigeria (31), and Egypt (33) in contrast to studies conducted in India (11, 27, 37, 39), Iraq(26) and Tanzania(34) where hemoglobin count didn't show any significant difference between cases and controls. The incidences of polycythemia among newborns of hypertensive mothers were higher than normotensive mothers. Similar results were seen in studies conducted in Nigeria (31) and Egypt (33) unlike studies conducted in India(29), Sudan(35) and Nigeria(32) where no significant incidence of polycythemia was observed. The etiology underlying for elevated RBC, HgB and HCT counts among newborns of hypertensive mothers is that PIH results in state of compromised blood supply to the fetus. Compromised blood flow creates tissue hypoxia and oxidative stress to the placenta. This condition brings in compensatory mechanism that leads to elevated erythropoiesis (4, 8).

In the present study, the median MCV and MCH counts were significantly higher in the study group than control groups. The findings were similar with studies conducted in India(37) and Sudan(35). In contrast, no significant difference were observed in MCV, MCH and MCHC counts of newborns of hypertensive mothers in studies conducted in Turkey(24), Nigeria(32) and India(11). The probable reason could be hyper stimulation of red cell production in response to tissue hypoxia and oxidative stress in the placenta. Another possible mechanism for elevated MCV and MCH could be larger size of RBC's in preterm neonates born prematurely from hypertensive mothers (27). Furthermore, the median RDW was higher in newborns of

hypertensive mothers compared to normotensive. Similar findings were observed in studies conducted in India(11) and Turkey(24).This might be due to tissue hypoxia which results in enhanced erythropoiesis and increases in circulating both mature and immature RBC in fetal circulation. This results in heterogeneity of RBC and elevated RDW in newborns(24) .

In the current study, the median platelet counts of newborns of hypertensive mothers were significantly lower than that of normotensive mothers. The incidence of thrombocytopenia among study group was higher compared to control group. The findings were consistent with various studies conducted in India(27, 28, 37-39, 42, 43), Turkey(24), Nigeria (31, 32), Tanzania(34), Sudan (35) and Egypt(33). The etiology underlying for neonatal thrombocytopenia secondary to PIH is that: hypertension causes fetal hypoxia which in return enhance erythropoiesis. Exposure to high level of erythropoietin might consume stem cells for production of megakaryocytic cell line which will decrease platelet production. In addition, thrombocytopenia could occur as a result of platelet adherence to the damaged endothelial region caused by vasodilation in the placenta of hypertensive mothers. The cumulative effect of increased consumption and decreased production might result in neonatal thrombocytopenia(33).

The current study showed that the median platelet counts of newborns were significantly differ between gestational hypertension and preeclampsia subtypes. Similar findings were observed in studies conducted in Turkey(24) and India(42). This could be due to the fact that vascular complications worsen with longer duration of hypertension. Longer exposure to maternal hypertension increases platelet consumption and decreases platelet production which directly affects the platelet count of newborn(42).

In the current study, platelet counts of hypertensive mothers were significantly lower than normotensive mothers. Low platelet count of hypertensive mothers is due to increased platelet consumption following the damage to the endothelium, reduced life span of circulating platelet in periphery and the altered platelet membrane accelerates its increased aggregation of platelets(51, 52).

In the present study, platelet counts of newborns of hypertensive mothers were significantly and negatively correlated with diastolic blood pressure of their mothers. This could be due to the fact that severe maternal hypertension results in elevated blood pressure which in return lowers

platelet count. This finding is consistent with studies conducted in Bangladesh(46) and Sudan(35). The other parameters didn't show any significant correlation between either systolic or diastolic blood pressure. In this study, RBC and MCV counts were positively correlated with weight of the newborn. The possible reason is that maternal hypertension has a direct effect on both neonatal hematological profiles and weight of the newborn which brings a cumulative effect on RBC and MCV counts. In addition, platelet counts of cases were positively correlated with gestational weeks of delivery. The finding was consistent with study conducted in Romania (41). The probable reason is PIH has a direct effect on premature birth which in return affects the platelet counts. In contrast MCH counts were negatively correlated with gestational week of delivery. This might be due to the fact that MCH value tends to get lower as gestational week of delivery increases (53).

In the present study, monocyte counts of newborns were positively correlated with maternal monocyte count. This might be due to enhanced maternal inflammatory condition in hypertensive disorder results in increased cytokine synthesis IL-6 in both maternal and fetal circulation. This in return is directly associated with fetal monocyte(54) . In contrast RBC counts of newborns were negatively correlated with maternal RBC counts. The probable reason might be pregnancy-related physiological changes that modify blood's chemical composition, accelerate shift of some hematopoietic micronutrients, and increase its consumption as defensive mechanisms against pregnancy related oxidative stress results in maternal low hematological values while increasing fetal erythropoiesis. This finding is inconsistent with studies conducted in Sudan (55) where no significant correlation between maternal and newborns RBC's were observed.

8. Strength and limitation of the study

This study is pioneer to assess the hematological profiles of newborns of hypertensive mothers in Addis Ababa. Furthermore, assessment of neonatal outcome soon after delivery can be considered as strength of the study. However, the present study had few limitations. Follow up of the neonates after neonatal intensive care unit admission and follow up for hematological

abnormalities were not done. Furthermore, enumerations of NRBC were not analyzed because of financial constraints.

9. Conclusion and recommendation

9.1 conclusions

RBC, HgB, MCV, MCH, Lymphocyte and RDW SD counts were significantly higher in newborns of hypertensive mothers compared to normotensive mothers. The median platelet counts of cases were significantly lower compared to the control groups. No significant difference were seen in WBC, neutrophil, monocyte, basophil, eosinophil and MPV counts between newborns from hypertensive and normotensive mothers. The median platelet counts of newborns had a significant difference between gestational and preeclamptic subtypes. Newborn RBC and MCV counts were positively correlated with birth weight. Platelet counts was positively correlated with gestational age while, MCH was negatively correlated with it. In the cases, maternal and newborn monocyte count showed statically significant positive correlation whereas RBC counts showed negative correlation.

9.2 Recommendations

Early hematological screening for newborns of hypertensive mothers is recommended to assist in detection, prevention and management of early neonatal complications. It is suggested that laboratories and stakeholders should incorporate examination of cord blood into their routine test panel in order to decrease morbidity and mortality of newborns. A further research with longitudinal follow up of newborns is encouraged to know the long term effect of pregnancy induced hypertension on hematological profiles of neonates.

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11. Annexes

Annex 1. – Standard Operating Procedure (SOP)

Procedures for Cord Blood Collection

1. Prepare all the necessary materials like needle and syringe and put them in place within safe and easily reachable materials like tray and trolley
2. Put on well-fitting gloves
3. After delivery of the newborn, double-clamped the umbilical cord and cut.
4. Remove any blood from the surface of the cord with gauze
5. Insert the needle just above the clamp that remains on the cord
6. After collecting sufficient amount of blood, withdraw the needle gently.
7. label test tube with the medical registration number and date
8. Discard the used needle and syringe or blood-sampling devices into a puncture resistant container.
9. Dispose the used gloves appropriately

SOP for Sysmex XN550 hematology analyzer

1. Purpose: To determine complete blood count using Sysmex XN550 automated hematology analyzer

2. Principle: The Sysmex XN-550 is multi-parameter quantitative automated hematology analyzer for in vitro diagnostic use in determining whole blood diagnostic parameters. The devices perform hematology analyses based on the hydrodynamically focused impedance measurement, the flow cytometry method (using a semiconductor laser) and the SLS-hemoglobin method. The impedance technology is based on the principle that an electrical field, created between two electrodes of opposite charge, can be used to count and determine the size of cells. Blood cells are poor conductors of electricity. The diluent in which they are suspended as they pass through the aperture during counting is an isotonic solution which is a good conductor of electricity. Consequently, when the cells suspended in the diluent pass through the aperture between the electrodes, each individual cell will momentarily increase the impedance (resistance) of the electrical path between the electrodes. Each cell generates an electrical pulse; in proportion to its size. The device counts and sizes red blood cells (RBC) and platelets (PLT) using hydrodynamic impedance counting (sheath flow DC method). At the same time the

hematocrit (HCT) is measured as a ratio of the total RBC volume to whole blood via the RBC pulse height detection method. Flow cytometry is a method used to analyze those cells and particles as they pass through extremely small flow cells with light beam. The angle of light scattered when striking a cell depicts cell size and/or yields information about cellular characteristics: cell size and granularity

3. Materials

A. Supplies

- ✚ Lint-free lined lab wipes
- ✚ Gauze
- ✚ Test tubes
- ✚ CELLCLEAN® AUTO
- ✚ Commercial controls; XN CHECK™

B. Sysmex Reagents

✚ **Diluents:**

- ❖ CELLPACK DCL: Whole blood diluent for use in hematology analyzers.

✚ **Lysing Reagents**

- ❖ Sulfolyser (SLS): is a lysing reagent that releases the hemoglobin to be measured by the SLS method.
- ❖ Lysercell WDF: Reagent product to be combined and used with Fluorocell WDF. By hemolyzing red blood cells with Lysercell WDF and dyeing the white blood cell component with Fluorocell WDF then counts and percentages of neutrophils, lymphocytes, monocytes, eosinophils and basophils are analyzed.

✚ **Staining Reagents**

- ❖ Fluorocell WDF: Used to stain the leukocytes in diluted and lysed blood samples for determination of differential count in blood.

✚ **Cleaning Agent**

- ❖ CELLCLEAN AUTO: Detergent for fully automated hematology analyzers. To be used as a strong alkaline detergent to remove lysing reagents, cellular residuals, and blood proteins remaining in the hydraulics of the analyzer on XN Series/XN-L Series automated hematology analyzers.

1. Sample

A. Required specimen

- ✚ Whole blood anticoagulated with a potassium EDTA is preferred.
- ✚ Sodium Citrate may be used when EDTA platelet clumping or platelet satellitism is noted on the EDTA specimen. Platelet counts, immature platelet fraction and WBC counts are the only parameters that may be resulted from the Sodium Citrate specimen. If reporting results from the Sodium Citrate specimen, attach canned comment (Citrated sample. Results may vary from EDTA).

B. Specimen volumes required

- ✚ Optimal draw is a tube drawn to capacity. The collection tube must be filled to a minimum of one-half full for acceptable results.
- ✚ A minimum of 1 mL of whole blood is required for sampler analysis.
- ✚ An EDTA raised bottom microtainer filled above the 250 uL line is adequate. A standard EDTA microtainer must contain 160 uL, though to maintain the proper anticoagulant ratio it must have been filled to the 250 uL line at the time of collection.

C. Characteristics that may affect test results:

- ✚ Lipemia (may falsely increase HGB)
- ✚ Icterus (may falsely increase HGB)
- ✚ Cold agglutinins (may falsely increase WBC count, MCV and MCHC; may falsely decrease HCT & RBC count)
- ✚ Severe hyponatremia (decreased plasma sodium level) may falsely decrease HCT causing a falsely increased MCHC.

D. Stored Specimen Stability

- ✚ If stored at 4-8oC within 6 hours of collection, EDTA blood samples with normal results may be analyzed up to 48 hours without significant loss of differential stability. The stability may be increased to 72 hours if results do not show a loss of specimen integrity.
- ✚ Slides for a manual differential must be assessed for cellular integrity prior to reporting. If cellular integrity is not intact a manual differential or morphology should not be reported

5. Special safety precautions:

- ✚ Wear protective clothing
- ✚ Follow infection prevention principle during sample handling
- ✚ Wear gloves for handling blood or serum
- ✚ Decontaminate working area with 0.5% bleach solution
- ✚ Change gloves when they become contaminated
- ✚ Wash hands after handling specimens
- ✚ CELLCLEAN is a strong alkaline detergent; take care not to have it adhere to the skin or clothes. If the skin or clothes should come in touch with it, flush it away using plenty of water. Otherwise, it can damage the skin or clothes.

6. Quality control: Quality Control checks are performed to monitor an instrument's performance over time. Quality control material is supplied with three control levels; at least two levels should be run every 8 hours of operation or in accordance to regulations applicable to your laboratory. Quality control material should be run after component replacement or after a service call.

7. Procedures

Inspection of reagents: Check to see that the reagents needed for the number of the samples to be processed for the day are available (1 Liter of CELLPACK for 30 samples and 50 mL of STROMATLYSER-WH for 47 samples in whole blood analysis mode are enough)

Inspection of the instrument: Inspect the connection of tubing and cords to see that there are no broken tubes and the power cord is properly plugged in the outlet

Inspection of waste: If waste is found to have collected in the trap chamber on the left side of the unit and the waste tank, discard the waste.

Inspection of printer paper: Open the front cover and check if printer paper needed for processing the samples for the day is available

Turn on the power and wait for the result of self-check: Permissible background count

- ✚ WBC $0.10 \times 10^3 / \mu\text{L}$
- ✚ RBC $0.02 \times 10^6 / \mu\text{L}$
- ✚ HGB 0.1 g/dL

✚ PLT 10 [X 10³/mL] or less

Selecting whole blood mode

- ✚ Confirm the “READY” status on LCD
- ✚ Press [MODE] key to display the Change Mode screen
- ✚ Press [←] or [→] key to select "Whole Blood (WB)."
- ✚ Press [ENTER] key to changeover the analysis mode and return to the Analysis screen

Inputting Sample/ID number

Press [SAMPLE No.] key in the Ready status. In the system status area on the LCD screen, the next sample No. turns to the reverse display and the system is waiting for Sample No..The cursor appears under sample No. Input sample number using the numeric keys .Press [ENTER] key, this will fix the sample No. and the status becomes ready, namely, ready for analysis

Analyzing samples

- ✚ Mix the sample sufficiently
- ✚ Remove the plug while taking care not to allow blood scatter
- ✚ Set the tube to the sample probe, and in that condition, press the “START” switch
- ✚ The buzzer sounds two times - "beep, beep" and when the LCD screen displays "Analyzing," remove the tube. After that, the unit executes automatic analysis and displays the result on the LCD screen. Then the unit turns to the “READY” status, becoming ready for analysis of the next samples.

Display and printing of analysis result

- ✚ The result of each analysis is displayed on the LCD screen
- ✚ The display screen of analysis result consists of three pages, and pages are turned over by using [←] or [→] key
- ✚ Analysis result can be printed out on the built-in printer

8. Limitations

- ✚ Specimens must be free of clots and fibrin strands.
- ✚ Marked changes in plasma constituents (e.g., low sodium, extremely elevated glucose) may cause cells to swell or shrink. The blood to anticoagulant ratio is important.

- ✚ Red cell fragments, microcytic RBCs or white cell cytoplasmic fragments may interfere with automated platelet counts.
- ✚ Cold agglutinins produce spurious macrocytosis, elevated MCHs MCHCs, falsely decreased RBC counts and HCTs. Rare warm agglutinins produce the same spurious results as a cold agglutinin.
- ✚ Extremely elevated WBCs may cause turbidity and falsely increase the hemoglobin, in addition to RBC and HCT values.
- ✚ Hemolyzed samples (in vitro) falsely decrease RBC and hematocrit.
- ✚ Giant platelets and clumped platelets may falsely elevate the WBC count and falsely decrease the platelet count. Platelet clumping and/or "platelet satellitism" can occur in specimens collected in EDTA. This may falsely elevate the WBC count and falsely decrease the platelet count.
- ✚ Abnormal paraproteins found in blood from patients with Multiple Myeloma can falsely increase the HGB.
- ✚ Severely icteric samples may falsely elevate the HGB value and related indices.
- ✚ Megakaryocytes may falsely increase WBC counts on automated hematology analyzers

9 interpretations

- ✚ Low level of Hgb seen in patient with anemia and the different red cell parameters give for the possible type of etiology.
- ✚ Elevated white blood cell count may indicate infection.
- ✚ Decreases in white blood cell count may occur with disease progression or may indicate bone marrow suppression from ARV therapy.
- ✚ Total lymphocyte count: After a patient is on ARV therapy, a decrease in Absolute lymphocyte count may reflect bone marrow suppression from treatment.
- ✚ Total lymphocyte count of < 1,200/ml has been correlated with a CD4 count of less than 200/ml. However, the total lymphocyte count alone shouldn't be used in asymptomatic patients when deciding whether to start ARV therapy.
- ✚ An increase in neutrophils may be due to an acute bacterial infection or hematological malignancies such as Myeloid Leukemia.
- ✚ An increase in eosinophils may be due to a parasitic infection or an allergic Reaction.
- ✚ An increase in lymphocytes may be due to viral infections or chronic infection

Annex 2 – Subject Information Sheet (For Pregnant Mothers, English Version)

Addis Ababa University

College of Health Sciences

Department of Medical Laboratory Sciences

Subject Information Sheet for Mother Whose Cord Blood is to be used for neonatal hematological profiles

You are invited to participate in a study to be conducted by MSc student at Addis Ababa, College of Health Sciences, Department of Medical Laboratory Science. Please read the following statements and ask any unclear points before you agree to participate.

Introduction

The topic of this study is hematological profiles of neonates born with and without preeclampsia at Gandhi memorial hospital from July to September 2022. The aim of the study is to determine hematological profiles of neonates born with preeclamptic and normotensive mothers and the obtained values can be used as diagnostic and prognostic marker in certain neonatal complications in early life.

Participation in this study is exclusively voluntarily. If you are not interested to participate or if you once decide to participate and withdraw at any time, there will be no consequences and you will get all the services provided in the hospital with no problems. If you decide to participate, you have to sign on the consent form and you may obtain a copy of this information sheet.

What is expected from me as a participant of the study?

As a participant of this study, you are expected to agree that 2-3mL blood will be collected from the cord immediately after your delivery before the expulsion of the cord. In addition, you are expected to give answers for some questions about your health and socio-demographic conditions. You need to know that your results might be discussed with other appropriate individual out of this hospital. But your name, address and phone number will not be disclosed and rather than identification code will be used in such conditions.

How much time will I spent to participate in this study?

You will spend 20-25 minutes until the specimen is collected, the consent form is signed and the questionnaire is filled.

What are the risks of participating in this study?

The sample collection will pose minimal pain on you and the only thing you spend is just your time to fill the questionnaire

How my information is to be kept in secret?

All information that you give and the results from your sample will be used for this study only, only limited numbers of professionals will have access to the information. All the information will be encoded in a computer and saved with password protection.

What are the benefits from participation?

Since this study is MSc student research, there will not be payments for participants. But your participation is important for determination of neonatal hematological profiles secondary to preeclampsia which is useful to improve the clinical management of neonatal complications with no additional cost.

What are my rights as a participant of this study?

You have the right to withdraw yourself from the study at any time and all the services provided in the hospital will not be discontinued. You are also welcomed if you have any questions for further explanations about the study. You may also get the results of the analysis.

What can I do if I have a problem or a question?

Please direct any questions or problem you may encounter during this study to:

Melat Mekonnen

Department of Medical Laboratory Sciences,

College of Health Sciences, Addis Ababa University

Mob: +251922598435

Email: melimekonnen@gmail.com

Advisors: Mr. Zemenu Tamir 0915992362; Mr. Moges Wordofa 0984742173

For additional information, please contact Department of Medical Laboratory Sciences,
Addis Ababa University, Institutional Review Board (IRB) office; Tel: +2511911107099
P.O Box: 9086, Addis Ababa, Ethiopia

Agree to participate? Yes

No

Annex 3 – Subject Information Sheet (For Pregnant Mothers, Amharic Version)

አዲስ አበባ ዩኒቨርሲቲ

የጤና ሳይንስ ኮሌጅ

የሕክምና ላቦራቶሪ ሳይንስ ት/ክፍል

ከእትብት ላይ ደም ተወስዶ ለሚሰራው የጨቅላ አጠቃላይ የደም ምርመራ (CBC) ውጤት ጥናት ለሚሰተፉ እናቶች የተዘጋጀ መረጃ

አዲስ አበባ ዩኒቨርሲቲ፣ የጤና ሳይንስ ኮሌጅ፣ የሕክምና ላቦራቶሪ ሳይንስ ት/ክፍል በማስተርስ ዲግሪ ተማሪ የመመረቅ ጥናት ላይ እንዲሰተፉ ተጋብዘዋል። እባክዎ በዚህ ጥናት ለመሳተፍ ከመስማማትዎ በፊት ከዚህ ቀጥሎ የሚገኘውን ምንባብ በጥሞና ያንብቡና ግልፅ ያልሆነልዎትን ማንኛውም ሃሳብ ይጠይቁ።

መግቢያ

የጥናቱ ርዕስ በእትብት የደም ናሙና ላይ የሚሰራ የጨቅላ አጠቃላይ ደም ምርመራ (CBC) ውጤት ነው። ለማውጣት ደም ግፊት ካለባቸው እናቶች የጨቅላ ህፃናትን አጠቃላይ ደም ምርመራ ውጤቶች ማወዳደሪያ ዋጋ ማግኘት ሲሆን ጥቅሙም ጨቅላ ህፃናትና አዲስ ለተወለዱ ህፃናት የሚኖራቸውን የእነዚህን አጠቃላይ ደም ምርመራ ውጤቶች ዋጋ በትክክል ለመተርጎም ይደረጋል።

እርስዎ በዚህ ጥናት ላይ የሚኖርዎት ተሳትፎ ሙሉ በሙሉ በበጎ ፈቃደኝነት ላይ የተመሰረተ ሲሆን በዚህ ጥናት ውስጥ ላለመሳተፍ ሆነ ለመሳተፍ ከወስኑ በኋላ ለማቋረጥ የሚወስኑ ቢሆንም እንኳን በዚህ ሆስፒታል ውስጥ የሚገኝ ማንኛውም አገልግሎት አይቋረጥም። በጥናቱ ለመሳተፍ ከፈለጉ የስምምነት ቅጹ ላይ በፅሁፍ ወይም በጣት ፊርማ ማረጋገጥ ይኖሩበታል። ከፈለጉም ይህን የመረጃ ቅፅ አንድ ቅጂ ለራስዎ መውሰድ ይችላሉ።

በጥናቱ ተሳታፊ በመሆኔ የሚጠበቅብኝ ምንድን ነው?

በዚህ ጥናት ላይ ለመሳተፍ የሚስማሙ ከሆነ 2-3ሚ.ሊ የደም ናሙና በሚወልዱበት ጊዜ ከእትብት ላይ እንደሚወሰድ እና ለጥናቱ እንደሚወልድ መስማማት ይጠበቅበታል። ከተወሰደው ናሙና ላይ የሚገኙ መረጃዎች ከዚህ ሆስፒታል ውጭ ለሚገኙና ለስራው አግባብነት ላላቸው ሰዎች ቢነገር የማይቃወሙ መሆኑን መስማማት ይጠበቅበታል። የስልክ ቁጥር የመሳሰሉትን መረጃዎችን አይጨምርም። ይልቁንም ለዚህ ጥናት አገልግሎት ብቻ የሚወልድ እርስዎን ለማወቅ የሚያስችል መለያ ቁጥር ጥቅም ላይ እንዲወልድ ይደረጋል። በተጨማሪም ስለ እርስዎ አጠቃላይ የጤና ሁኔታ ለሚቀርቡ አንዳንድ ተጨማሪ ጥያቄዎች መልስ መስጠት ይጠበቅበታል።

በዚህ ጥናት መሳተፍ ምን ያህል ጊዜ ይፈጃል?

የተዘጋጀውን መጠይቅ ለመሙላት የስምምነት ቅጹ ላይ ለመፈረም ከ20-25ደቂቃ ያስፈልጋል።

በዚህ ጥናት መሳተፍ የሚያስከትላቸው ችግሮች ምንድን ናቸው?

ናሙና በሚወሰድበት ጊዜ ምንም አይነት የህመም ስሜት አያስከትልብዎትም ስለዚህም የሚያጡት ነገር ቢኖር መጠይቁን ለመሙላት የሚያጠፉት ጊዜ ነው።

የህክምና መረጃዬ በሚስጢር ተጠብቆ መቆየት የሚችለው እንዴት ነው?

ስለራስዎ የሰጡት ማንኛውም መረጃና ከተወሰደው ናሙና ላይ የተገኘው የላቦራቶሪ ውጤት የሚውለው ለጥናቱ አላማ ብቻ ነው። ይህን ማህደር ሊያገኙ የሚችሉት የተወሰኑ የጥናቱ ተባባሪ ሰራተኞች ብቻ ናቸው። ከዚያም በላይ ስለእርስዎ ያለውን ማንኛውም መረጃ የተለየ የይለፍ ቃል ባለው ኮምፒዩተር የመረጃ ማህደር ውስጥ እንዲቀመጥ ይደረጋል።

በዚህ ጥናት ላይ መሳተፍ የሚያስገኛቸው ጥቅሞች ምንድን ናቸው?

ይህ ጥናት የማስተርስ ዲግሪ ተማሪ መመረቂያ እንደመሆኑ መጠን ለተሳታፊዎች ገንዘብ አይከፈልም፤ ነገር ግን የእርስዎ ተሳትፎ አዲስ የሚወለዱ ህፃናትን ለመርዳትና በህፃናቱ ላይ የተገኘውን የአጠቃላይ ደም ምርመራ ውጤቶችን ለመተርጎም ይጠቅማል።

በዚህ ጥናት ተሳታፊ በመሆኔ መብቶቼ ምንድን ናቸው?

በጥናት ውስጥ ያልዎትን ተሳትፎ በማንኛውም ጊዜ የማቋረጥሙሉ መብትዎ የተጠበቀ ከመሆኑም በላይ ራስዎ ከጥናቱ በማግለልዎ ምክንያት ምንም አይነት የሆስፒታሉ አገልግሎት አይቋረጥብዎትም። ከዚህም በተጨማሪ ጥናቱን በተመለከተ ማንኛውም ጥያቄ የመጠየቅና ገለፃ የማግኘት መብት አለዎት። የላቦራቶሪ ምርመራ ውጤቱንም በነፃ ማግኘት ይችላሉ።

ጥያቄ ካለኝ ወይም ችግር ቢያጋጥመኝ ምን ማድረግ ይገባል?

ይህን ጥናት በተመለከተ ወይም ከዚህ ጥናት ጋር በተዛመደ መልኩ ስለሚያጋጥሙ ድንገተኛ አደጋዎች ወይም ጥያቄ ካልዎት በሚከተለው አድራሻ ይጠቀሙ።

የህክምና ላቦራቶሪ ሳይንስ ት/ክፍል፤

የጤና ሳይንስ ኮሌጅ አዲስ አበባ ዩኒቨርሲቲ

ማላት መኮንን

ሞባይል: +251922598435 ኢሜይል: melimekonnen@gmail.com

ጥናት አማካሪዎች: **ዘመነ ታምር** 0915992362 ፤ **ሞገስ ወርዶፋ** 0984742173

ለተጨማሪ መረጃ የአዲስ አበባ ዩኒቨርሲቲ ህክምና ፋክልቲ ኢንስቲትዩሽናል ሪቪዩ ቦርድ ይጠይቁ።

ስ.ቁ: +2511911107099

ፋክስ: +251115511513099

ፖ.ሰ.ቁ: 9086 አዲስ አበባ ፤ ኢትዮጵያ

ለመሳተፍ ይስማማሉ?

እስማማለሁ

አልስማማም

Annex 4 – Consent Form (Pregnant Mothers, English Version)

Code Number-----

I have been informed about the study which is aimed to determine hematological parameters of cord blood. For this study blood is required from the cord. The aim of the study was explained to me. I am also informed that all the information contained within the questionnaire is to be kept confidential. Moreover, I have been well informed of my right to keep hold of information, decline to cooperate and make myself withdraw from this study. It is therefore, with full understanding of the situation that I gave the informed consent voluntarily to the researcher to use the blood taken from the cord for the investigation. In addition, I have also been informed that the benefit of the participation is to get the results of the analysis measured for free via the counselor.

Participant’s signature/ finger print-----

Name of deponent (mother unable to read) -----Signature-----Date---

Name of Counselor-----Signature-----Date-----

Please direct any questions or problem you may encounter during this study to:

Melat Mekonnen

Department of Medical Laboratory Sciences

College of Health Sciences

Addis Ababa University

Mob: +251922598435

Email: melimekonnen@gmail.com

Advisors: Mr.Zemenu Tamir; Mr.Moges

For additional information, please contact Department of Medical Laboratory Sciences,
Addis Ababa University, Institutional Review Board (IRB) office;
Tel: +2511911107099 P.O Box: 9086, Addis Ababa, Ethiopia

Annex 5 – Consent Form (For Pregnant Mothers, Amharic Version)

የስምምነት ቅጽ (ለእናት)

የምስጢር ቁጥር -----

እኔ ስሜ ከላይ የተጠቀሰው ተሳታፊ በእትብት ላይ ስለሚሰራው የአጠቃላይ ደም ምርመራ (CBC) ውጤት ጥናት በቂ ገለፃ ተደርጎልኛል። ለጥናቱም ከእትብት የተወሰደ የደም ናሙና እንደሚያስፈልግ ተገለጻል። የጥናቱን አላማዎችንም ተረድቻለው። በመጥይቁ ላይ የገለጻቸው መረጃዎች በሙሉ በምስጢር የተጠበቁ እንደሚሆኑ ተነግሮኛል። በጥናቱ ላይ ያለመሳተፍና ማንኛውም መረጃ ያለመስጠት እንዲሁም በማንኛውም ጊዜ ከጥናቱ እራሴን የማግለል መብቴ የተጠበቀ መሆኑን ተገለጻል። ስለዚህ ለዚህ ጥናት መረጃና የስምምነት ቃሌን የሰጠሁት በአጠቃላይ ሁኔታውን በመረዳትና ፍጹም ፈቃድኝነት ነው። ከእትብት ላይ የሚወሰደው ናሙና የልጁ/ጅቷ ጤና ሁኔታ ማወቅ እና ለምርመራ እንደሚውልም ተረድቻለው። በተጨማሪም ጥያቄ እንድጠይቅ ተፈቅዶልኝ ለማወቅ የፈለጉትን ማብራሪያ አንግቻለሁ። የዚህ ጥናት ተሳታፊ በመሆኔ የላቦራቶሪ ምርመራ በነፃ ማግኘት እንደሆነ ተረድቻለው።

የተሳታፊዎ ፊርማ/ የጣት አሻራ-----

የምስክር ስም----- ፊርማ----- ቀን-----

(የስምምነት ቅጹን ማንበብ ለማይችሉ ተሳታፊዎች)

የአማካሪ ስም-----ፊርማ----- ቀን-----

ይህን ጥናት በተመለከተ ወይም ከዚህ ጥናት ጋር በተዛመደ መልኩ ስለሚያጋጥሙዎትዎት አደጋዎች ወይም ጥያቄ ካልዎት በሚከተለው አድራሻ ይጠቀሙ።

ሜላት መኮንን

ሞባይል: +251922598435 ኢሜይል: melimekonnen@gmail.com

ጥናት አማካሪዎች: ዘመነ ታምር 0915992362 ፤ ሞገስ ወርዶፋ 0984742173

ለተጨማሪ መረጃ የአዲስ አበባ ዩኒቨርሲቲ ህክምና ፋክልቲ ኢንስቲትዩሽናል ሪሺዩ ቦርድ ይጠይቁ::ስ.ቁ: +2511911107099 ፋክስ: +251115511513099 ፖ.ሰ.ቁ: 9086፣ አዲስ አበባ፤ ኢትዮጵያ

Annex 6– Assent Form (Pregnant Mothers, English Version)

Code Number-----

I have been informed about the study which is aimed to determine hematological profiles of cord blood secondary to preeclampsia. For this study blood is required from the cord. The aim of the study was explained to me. I am also informed that all the information contained within the questionnaire is to be kept confidential. Moreover, I have been well informed of my right to keep hold of information, decline to cooperate and make myself withdraw from this study. It is therefore, with full understanding of the situation that I gave the informed consent voluntarily to the researcher to use the blood taken from the cord for the investigation. In addition, I have also been informed that the benefit of the participation is to get the results of the analysis measured for free via the counselor.

Participant’s signature/ finger print-----

Name of deponent (mother unable to read) -----Signature-----Date-----

Name of Counselor-----Signature-----Date-----

Please direct any questions or problem you may encounter during this study to:

Melat Mekonnen

Department of Medical Laboratory Sciences; College of Health Sciences Addis Ababa University

Mob: +251922598435

Email: melimekonnen@gmail.com

Advisors: Mr.Zemenu Tamir; Mr.Moges Wordofa

For additional information, please contact Department of Medical Laboratory Sciences, Addis

Ababa University, Institutional Review Board (IRB) office;

Annex 7 -Assent form (Amharic Version)

የስምምነት ቅጽ (ለልጁ/ጅቷ)

የምስጢር ቁጥር -----

እኔ ስሜ ከላይ የተጠቀሰው ተሳታፊ በእትብት ላይ ስለሚሰራው የአጠቃላይ ደም ምርመራ (CBC) ውጤት ጥናት በቂ ገለፃ ተደርጎልኛል። ለጥናቱም ከእትብት የተወሰደ የደም ናሙና እንደሚያስፈልግ

ተገለጻልኛል። የጥናቱን አላማዎችንም ተረድቻለው። በመጥይቁ ላይ የገለጻቸው መረጃዎች በሙሉ በምስጢር የተጠበቁ እንደሚሆኑ ተነግሮኛል። በጥናቱ ላይ ያለመሳተፍና ማንኛውም መረጃ ያለመስጠት እንዲሁም በማንኛውም ጊዜ ከጥናቱ እራሴን የማግለል መብቴ የተጠበቀ መሆኑን ተገለጻልኛል። ስለዚህ ለዚህ ጥናት መረጃና የስምምነት ቃሌን የሰጠሁት በአጠቃላይ ሁኔታውን በመረዳትና ፍፁም ፈቃድኝነት ነው። ከእትብት ላይ የሚወሰደው ናሙና የልጁ/ጅቷ ጤና ሁኔታ ለማወቅ እና ለምርመራ እንደሚውልም ተረድቻለው። በተጨማሪም ጥያቄ እንድጠይቅ ተፈቅዶልኝ ለማወቅ የፈለጉትን ማብራሪያ አንግቻለሁ። የዚህ ጥናት ተሳታፊ በመሆኔ የላቦራቶሪ ምርመራ በነፃ ማግኘት እንደሆነ ተረድቻለው።

የተሳታፊዎ ፊርማ/ የጣት አሻራ-----

የምስክር ስም----- ፊርማ----- ቀን-----

(የስምምነት ቅጹን ማንበብ ለማይችሉ ተሳታፊዎች)

የአማካሪ ስም-----ፊርማ----- ቀን-----

ይህን ጥናት በተመለከተ ወይም ከዚህ ጥናት ጋር በተዛመደ መልኩ ስለሚያጋጥሙዎትን ተገቢ አደጋዎች ወይም

ጥያቄ ካልዎት በሚከተለው አድራሻ ይጠቀሙ።

ሜላት መኮንን

ሞባይል: +251922598435 ኢሜይል: melimekonnen@gmail.com

ጥናት አማካሪዎች: ዘመነ ታምር 0915992362 ፤ ሞገስ ወርዶፋ 0984742173

Annex 8 – Questionnaire (For Pregnant Mothers, English Version)

Addis Ababa University

College of Health Sciences

Department of Medical Laboratory Sciences

Questionnaire for Data Collection from Mothers Whose Cord Blood is to be used for neonatal hematological determination

1. Introduction

Subject identification number ----- MRN -----

Age of the mother (in years) -----

Residential Place----- Tel: -----

2. Educational level

Unable to write and read College diploma/degree and above

Read and Write

Primary (1-8)

High School (9-12)

3. Occupation

Student House wife

Employed (government, NGO) Jobless

Private work Other (specify)

4. Marital status

Single Married Divorced Widowed

5. How many children previously delivered?

This is my first pregnancy

- 1 child
- 2 and above

6. If you delivered for question 5, on how many interval?

- 1 year
- 1 year 6 month
- 2 year
- 2 year and above

7. If yes for question 5, what was the mode of previous delivery?

- Normal spontaneous delivery
- Induced vaginal delivery
- Cesarean section

8. Did you drink alcohol during pregnancy?

- Yes No

9. If your answer for question 8 is 'yes', how often do you drink alcohol?

- Daily Every weekend occasionally

10. Did you smoke cigarettes during pregnancy?

- Yes No

11. If your answer is 'yes' for question 10, specify pack number smoked per day-----

12. Did you chew khat during pregnancy?

- Yes No

13. If your answer for question 11 is 'yes', how often do you chew chat?

- Daily Every weekend occasionally

14. Have you been sick for the last 3 months?

- Yes No

If yes, when ----- describe illness -----

15. Are you taking any prescribed medication?

Yes No

If yes, specify the name? -----

End of interview

Thank you!

Annex 9 – Questionnaire (For Pregnant Mothers, Amharic Version)

አዲስ አበባ ዩኒቨርሲቲ

የጤና ሳይንስ ኮሌጅ

የሕክምና ለቦራቶሪ ሳይንስ ት/ክፍል

ከእትብት ላይ ደም ተወስዶ ለሚሰራው የጨቅላ አጠቃላይ የደም ምርመራ ሁኔታ ጥናት ለሚሰተፉ እናቶች የተዘጋጀ መጠይቅ

1. መግቢያ

መለያ ቁጥር----- ካርድ ቁጥር -----

የእናት እድሜ (በአመት)-----

መኖሪያ አድራሻ -----

2. የትምህርት ደረጃ

ሀ. ማንበብና መፃፍ የማትችል መ. ሁለትኛ ደረጃ (9-12ኛ)

ለ. ማንበብና መፃፍ የምትችል ሠ. ኮሌጅ ሰርቲፊኬት/ዲፕሎማ/ድግሪ እና ከዛ በላይ

ሐ. መጀመሪያ ደረጃ (5-8ኛ)

3. የስራ ሁኔታ

9. ለ 8ኛው ጥያቄ መልስዎ እጠጣለሁ ከሆነ በየስንት ጊዜ ይጠጣሉ?

ሀ. በየቀኑ ለ. በሳምንቱ መጨረሻ ቀናት ሐ. አልፎ አልፎ

10. ሲጋራ ያጫሳሉ?

ሀ. አጫሳለሁ ለ. አላጫስም

11. ለ10ኛው ጥያቄ መልስዎ አዎ ከሆነ፤ ምን ያህል እሽግ በቀን ያጫሳሉ? -----

12. ጫት ይቅማሉ?

ሀ. እቅማለሁ ለ. አልቅምም

13. ለ11ኛው ጥያቄ መልስዎ እቅማለሁ ከሆነ በየስንት ጊዜ ይቅማሉ?

ሀ. በየቀኑ ለ. በሳምንቱ መጨረሻ ቀናት ሐ. አልፎ አልፎ

14. በአለፈው 3ወር ውስጥ ታመው ነበር?

ሀ. አዎ ለ. አልታመምኩም

አዎ ከሆነ መልስዎ መቸ?-----ህመሙ ምን እንደነበር ይግለጹ-----

15. መድሐኒት በመውሰድ ላይ ነዎት?

ሀ. አዎ ለ. አይደለም

ከወሰዱ የመድሐኒቱን ስም? -----

መጠይቁን ጨርሰዋል

አመሰግናለሁ!

Annex 10- Pregnant Mother and Newborn Medical and Diagnostic Information Sheet

Addis Ababa University

College of Health Sciences

Department of Medical Laboratory Sciences

Code Number -----

Physical examination of the Mother

Weight (in Kg) ----- Hypertension ----- Diabetes Mellitus -----

Gestational Week -----

Obstetric Problems -----

Laboratory & Diagnostic Test Results

Blood Type (ABO & Rh) -----

Complete Blood Count (CBC)

WBC ----- /uL LYM ----- % PDW-CV -----%

RBC ----- /uL MXD ----- %

HGB ----- g/dL NEU ----- %

HCT ----- % #LYM -----

MCV ----- fL #MXD -----

MCH ----- Pg #NEU -----

MCHC ----- g/L PLT ----- /uL

RDW-CV ----- % MPV ----- fL

Information about the Newborn

Gender Male Female

Current Delivery Mode -----Weight (in Kg) -----

Pulse Rate/min ----- Umbilical cord appearance -----

Annex-11 Laboratory Request and Result Report Form for Cord Blood

Addis Ababa University

College of Health Sciences

Department of Medical Laboratory Sciences

Code: -----

Blood Type (ABO & Rh) -----

Complete Blood Count (CBC)

WBC ----- /uL LYM ----- % PDW-CV -----%

RBC ----- /uL MXD ----- %

HGB ----- g/dL NEU ----- %

HCT ----- % #LYM -----

MCV ----- fL #MXD -----

MCH ----- Pg #NEU -----

MCHC ----- g/L PLT ----- /uL

RDW-CV ----- % MPV ----- fL

Initial & Sign. ----- Date -----

Sample Collector Initial & Sign. ----- Date -----

Declaration

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

M.Sc. candidate: Melat Mekonnen (B.Sc.)

Signature: _____

Date of submission: _____

This thesis has been submitted with our approval as advisors.

Advisor: Zemenu Tamir (MSc, PhD)

Signature: _____

Date: _____

Place: Addis Ababa, Ethiopia.

Advisor: Moges Wordofa (MSc)

Signature: _____

Date: _____

Place: Addis Ababa, Ethiopia.