MATERNAL AND PERINATAL OUTCOMES OF OLIGOHYDRAMNIOS IN TERM SINGLETON PREGNANCY IN JIMMA MEDICAL CENTER, SOUTH WEST ETHIOPIA: A COHORT STUDY



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A RESEARCH TO BE SUBMITTED TO THE DEPARTMENT OF OBSTETRICS AND GYNECOLOGY, INSTITUTE OF HEALTH SCIENCE, JIMMA UNIVERSITY IN PARTIAL FULFILLMENT OF THE REQUIREMENT FOR THE CERTIFICATE OF SPECIALITY IN OBSTETRICS AND GYNECOLOGY

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> NOVEMBER, 2022 JIMMA, ETHIOPIA

DECLARATION

I declare that this research thesis report entitled "MATERNAL AND PERINATAL OUTCOMES OF OLIGOHYDRAMNIOS IN TERM SINGLETON PREGNANCY IN JIMMA MEDICAL CENTER, SOUTH WEST ETHIOPIA: A COHORT STUDY" is my own work and has been carried out by me under the guidance and supervision of my Advisor's WOUBISHET GIRMA (MD, ASSOCIATE PROFESSOR OF OBSTETRICS AND GYNECOLOGY, GYNECOLOGIC ONCOLOGIST) and MISRA ABDULLAHI AHMED (BSC/PH, MPH/RH, PH.D., ASSOCIATE PROFESSOR OF REPRODUCTIVE HEALTH).

This thesis is original and has not been submitted for the award of any degree or diploma to any university or institution.

I understand that non-adherence to the principles of academic honesty and integrity, misconceptions/fabrications of any idea/data/source will constitute sufficient grounds for disciplinary action by the University and also evoke penal action from the sources which have not been properly cited or acknowledged

Researcher Name

Signature

Date

Dr. Darartu Fikire

CERTIFICATE

This is to certify that the thesis titled "MATERNAL AND PERINATAL OUTCOMES OF OLIGOHYDRAMNIOS IN TERM SINGLETON PREGNANCY IN JIMMA MEDICAL CENTER, SOUTH WEST ETHIOPIA: A COHORT STUDY". submitted to Jimma University, Department of Obstetrics and Gynecology for partial fulfillment of the requirement of specialty in obstetrics and gynecology and is a record of genuine research work carried out by Dr. Darartu Fikire, under my guidance and supervision.

Therefore, I hereby declare that no part of this thesis has been submitted to any other university or institution for the award of any degree or diploma and I approve that the report is submitted for implementation and further action as fulfilling the thesis requirement.

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As a member of the board of examiners of the Obstetrics and Gynecology thesis report open defense, we certified that we have read and evaluated the thesis report prepared by Dr. Darartu Fikire and examined the candidate's report. We recommend that the report be accepted for implementation and further actions as fulfilling the thesis requirements for Obstetrics and Gynecology Specialty.

Name of Examiners	<u>Signature</u>	Date

ABSTRACT

Background: Amniotic fluid encompasses the developing fetus, creating the perfect environment for healthy fetal growth and development. Oligohydramnios refers to the amniotic fluid volume that is less than the minimum expected for the gestational age. It's diagnosed by ultrasound examination, preferably based on an objective measurement such as amniotic fluid index (AFI) ≤5cm or single deepest pocket (SDP) <2 cm. Oligohydramnios can result from several congenital fetal defects, uteroplacental insufficiency, early membrane rupture, growth restriction, post-term pregnancy, chronic placental abruption, etc. Oligohydramnios can substantially impair fetal health, leading to issues including pulmonary hypoplasia and meconium aspiration syndrome, among others. The fetal prognosis depends on several factors, particularly the underlying cause, severity (reduced versus no amniotic fluid), and gestational age at the occurrence. Since there is no research on the effect of oligohydramnios in maternal and fetal outcomes in our setup, this study result will provide health professionals with an evidence-based decision.

Objective: To compare the Maternal and perinatal outcomes among women with oligohydramnios and normal amniotic fluid in term singleton pregnancy from March 2022 to Oct. 2022 among women managed at Jimma Medical Center, Jimma town, Southwest Ethiopia.

Method: A hospital-based prospective cohort study was conducted on term oligohydramnios pregnant mothers admitted to the labor ward from March 2022 to Oct. 2022. Purposive sequential enrolment of the test cohort after each study cohort was conducted and face-to-face interviews and patient chart reviews were conducted using a pretested structured questionnaire by trained medical interns and residents. Perinatal outcomes of the study participants were observed at admission, intrapartum, discharge, and 7 days following delivery. The telephone-based interview was used to complete data on 7 days postpartum for those discharged earlier. Data were collected by using KoBoToolbox and exported to SPSS Version 26 for data analysis. X^2 test, ANOVA, and independent t-test were used for comparisons, and logistic regression analysis is done. A 95% CI and P value < .05 were used to determine the level of statistical significance.

Result- The prevalence of oligohydramnios in this study period is 2.64% (109/4127). We found a significantly higher incidence of induced labor among women with oligohydramnios 42 (46.7%) compared to the non-oligohydramnios 14 (7.8%) ($X^2 = 70.051$, OR=.079 (.037-.168) p= <.001) and a higher rate of the caesarian section among women with oligohydramnios 48 (53.3%) compared to non-oligohydramnios the group 28 (15.6%) ($X^2 = 45.252$, OR=.150 (.072-.315) p= <.001) with a common indication of fetal distress 32 (35.6%) P = <.001. Compared to the nonexposed, Significant associations were found in birth weight <2500g among women with oligohydramnios 11(12.2%) compared to the nonexposed group 4 (2.2%) (P=.007) and perinatal outcome among women with oligohydramnios 26 (28.9%) compared to the nonexposed group 19 (10.6%) (P=.001). Five-minute APGAR Score < 7 among women with oligohydramnios 1 (1.1%) compared to the nonexposed group 0 (0%) (P=.320) and Neonatal intensive care unit (NICU) admission was required for 7 (7.8%) versus 17 (9.4%) neonates in oligohydramnios and non-oligohydramnios, respectively with a P value of 0.652 which is statistically not significant.

Conclusion: The prevalence of oligohydramnios is high. Oligohydramnios significantly impacts the onset of labor, mode of delivery, and adverse perinatal outcomes.

Keywords: Oligohydramnios, maternal outcome, perinatal outcome, matched case-control, term singleton pregnancy.

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Table of Contents

ABSTRACT	III
ACKNOWLEDGMENT	VII
TABLE OF CONTENTS	VIII
LIST OF TABLES	IX
LIST OF FIGURES	IX
<u>CHAPTER ONE – INTRODUCTION</u>	1 -
1.1 BACKGROUND	1 -
1.2 STATEMENT OF THE PROBLEM	3 -
1.3 SIGNIFICANCE OF THE STUDY	4 -
<u>CHAPTER TWO – LITERATURE REVIEW</u>	5 -
2.1 CONCEPTUAL FRAMEWORK	10 -
<u>CHAPTER THREE – OBJECTIVE</u>	11 -
3.1 GENERAL OBJECTIVE	11 -
3.2 SPECIFIC OBJECTIVES	11 -
CHAPTER FOUR -METHODOLOGY	12 -
4.1 Study area and Period	12 -
4.3 SOURCE POPULATION	12 -
4.4 STUDY POPULATION	13 -
4.4.1 INCLUSION CRITERIA	13 -
4.4.2 EXCLUSION CRITERIA	13 -
4.5 SAMPLE SIZE DETERMINATION	14 -
4.6.1 Study variables	15 -
4.6.1.1 Dependent variable	15 -
4.6.1.2 Independent variable	15 -
4.7 DATA COLLECTION	15 -
4.7.1 DATA COLLECTION INSTRUMENT	15 -
4.7.2 DATA COLLECTOR	16 -
4.7.3 DATA COLLECTION PROCEDURE	16 -
4.8 DATA PROCESSING AND ANALYSIS	16 -
4.9 DATA QUALITY CONTROL	17 -
4.10 Measurement	17 -
4.11 OPERATIONAL DEFINITION	17 -
4.12 DATA ETHICAL ASSURANCE	18 -
4.13 UTILIZATION AND DISSEMINATION OF RESULTS	18 -
5. RESULTS	<u> 19 -</u>
6. DISCUSSION	<u> 24 -</u>
7. CONCLUSION	26 -
8. RECOMMENDATION	<u> 26 -</u>
9. STRENGTH AND LIMITATION	<u> 26 -</u>
ANNEX I	<u> 27 -</u>
KEFERENCES	27 -
ANNEX II	<u> 29 -</u>
QUESTIONNAIRES	29 -

LIST OF TABLES

Table 5.1: Socio-Demographic Characteristics of women who were admitted to Jimma Medical Center, South West Ethiopia, from March. 2022 to Oct. 2022....- 19 - Table 5.2: Comparison of obstetric history between exposed and nonexposed women who were admitted to Jimma Medical Center, South West Ethiopia, from March. 2022 to Oct. 2022...- 20 - Table 5.3: Comparisons of maternal outcome between exposed and nonexposed women who were admitted to Jimma Medical Center, South West Ethiopia, from March. 2022 to Oct. 2022...- 22 - Z2 -

Table 5.4: Comparisons of Perinatal Outcome between exposed and nonexposed who were managed in Jimma Medical Center, South West Ethiopia,2022. Using Independent T-test....- 23 -

LIST OF FIGURES

ACRONYMS AND ABBREVIATIONS

AFI	Amniotic fluid index					
CS	Caesarean Section					
ENND	Early Neonatal D	eath				
FHR	Fetal Heart Rate					
GA	Gestational Age					
IUFD	Intrauterine Fetal	Death				
IUGR	Intrauterine Growth Restriction					
JMC	Jimma Medical Center					
LBW	Low Birth Weight					
LSCS	Lower uterine segment cesarean section					
MAS	Meconium aspiration syndrome					
NICU	Neonatal Intensive Care Unit					
SDP	Single deepest pocket					
SPSS	Statistical	Package	for	Social	Sciences	

CHAPTER ONE – INTRODUCTION

1.1 BACKGROUND

A clear, slightly yellowish liquid called amniotic fluid surrounds the fetus throughout pregnancy. The fetus floats in the amniotic fluid inside the uterus, where it is enclosed in the amniotic sac. The fetus continuously "inhales" and then "exhales" the amniotic fluid as it moves (1).

The amniotic fluid acts as a cushion for the fetus and shields it from physical and biological harm, creating a safe environment for fetal growth. It offers space for appropriate movement and development as well as the nutrients necessary for growth. The normal development of the respiratory, genitourinary, gastrointestinal, and musculoskeletal systems depends on amniotic fluid (2).

Oligohydramnios is defined as a liquor volume below the fifth percentile at that gestational age. Early-onset oligohydramnios is typically associated with congenital fetal anomalies, including dysplastic kidney, obstruction of the bladder outlet, bilateral renal agenesis, pulmonary hypoplasia, bilateral multicystic kidney, etc., and is associated with poor fetal outcomes, including intrauterine growth restriction, facial distortion, and multiple structural deformities. Women with late-onset oligohydramnios are more likely to experience a placental anomaly or maternal problems like preeclampsia or vascular disorders because the condition is mostly caused by thick meconium fluid and umbilical cord compression (2).

Every normal obstetric ultrasonography examination and antepartum fetal surveillance should include an assessment of the amniotic fluid volume. At 12 weeks, it measures roughly 50 ml, at 20 weeks, 400 ml, and at 36 to 38 weeks, it reaches its peak volume of 1 liter. After that, it gets smaller until term, when it's around 600-800 ml. The intrusive dye dilution technique, which is the industry standard, can be used to measure the volume of amniotic fluid. The four-quadrant amniotic fluid index (AFI), single deepest pocket (SDP), and two-diameter pocket via ultrasound examination are additional non-invasive techniques. The amniotic fluid content of 5% for gestational age, AFI 5 cm, or the greatest deepest pocket of 2 cm are all examples of oligohydramnios. The most accurate approach for oligohydramnios diagnosis is the single

deepest pocket; AFI is used in the majority of studies examining negative consequences, nevertheless. The discovery of oligohydramnios is abnormal regardless of the method used (3,4).

Numerous congenital fetal abnormalities, uteroplacental insufficiency, early membrane rupture, growth restriction, post-term pregnancy, chronic placental abruption, etc. can all contribute to oligohydramnios. Oligohydramnios can gravely harm a fetus, leading to issues such as pulmonary hypoplasia, meconium aspiration syndrome, fetal compression, and infections in cases of persistent membrane rupture. Low birth weight babies are more likely to be born to women who have oligohydramnios. In terms of the cost of treatment, oligohydramnios has also been linked to increased rates of cesarean births for fetal distress and neonatal admission to the critical care unit. Improvement in several maternal and fetal/newborn outcomes has been linked to prompt detection and treatment. When oligohydramnios is discovered, treatment options for affected women may include amnioinfusion, early labor induction, and even cesarean delivery (5).

Oligohydramnios is linked to a higher likelihood of unfavorable outcomes. Meconium aspiration syndrome (MAS), admission to the neonatal intensive care unit (NICU), a 5-min Apgar score of 7, an umbilical cord blood pH of 7.10, low birth weight (small-for-gestational age), and respiratory distress syndrome were all associated with adverse outcomes for the fetus. Maternal risks included increased rates of cesarean delivery due to meconium staining of amniotic fluid or fetal distress (5).

This study's goal is to identify the perinatal outcomes and maternal complications related to oligohydramnios.

1.2 STATEMENT OF THE PROBLEM

In the third trimester, low amniotic fluid volume is often found in 3-8% of pregnant women. Normally, it is seen as a symptom of placental insufficiency. About 1-5% of all pregnancies are found to have oligohydramnios (6). Due to the easy availability of ultrasonography today, oligohydramnios was discovered more frequently(7).

Lack of amniotic fluid at term is linked in obstetrics practice to several unfavorable antepartum, intrapartum, and postnatal mother pregnancy outcomes. For example, there is a higher chance of non-reactive non-stress tests, labor inductions, fetal heart rate decelerations during labor, meconium-stained amniotic fluid, cesarean delivery for fetal labor intolerance, stillbirths, NICU admissions, low Apgar scores, and neonatal mortality (8).

Most of the research on the topic has been limited to a few comparisons of pregnancy outcomes. For instance, a cross-sectional study conducted in Ethiopia showed the maternal and perinatal effects of oligohydramnios during the third trimester of pregnancy. However, these findings solely considered data from cases of oligohydramnios to conclude the existence of a substantial correlation between poor perinatal and maternal outcomes(8). Surprisingly, little research has been done on the impact of oligohydramnios. It is still unclear how oligohydramnios affects maternal and perinatal outcomes when compared to normal amniotic fluid in term singleton pregnancies utilizing a matched case-control approach.

1.3 SIGNIFICANCE OF THE STUDY

Recent research in the study region has not compared the maternal and perinatal outcomes of term singleton pregnancies with oligohydramnios and normal amniotic fluid. This study will therefore provide new information about the effects of oligohydramnios and normal amniotic fluid in term singleton pregnancy on maternal and perinatal outcomes. The results of this study will also assist medical professionals to provide a better understanding of our context and in advising mothers about potential outcomes so they may make an educated choice. The results of our study will assist national guidelines being developed by policymakers to improve the perinatal outcome of oligohydramnios. Furthermore, by providing a starting point for additional investigations, these research findings will significantly advance the field of maternal and child health research.

CHAPTER TWO – LITERATURE REVIEW

Maternal outcomes of oligohydramnios

Oligohydramnios is a condition when the amount of fluid enveloping the fetus in the uterus is inadequate.

According to a Chinese study, pregnancies with diagnosed oligohydramnios had a considerably higher cesarean delivery (CD) rate than those without (84.4 versus 54.7 percent; p.001). Additionally, in 2/3 of these cesarean deliveries in oligohydramnios-positive pregnancies, oligohydramnios was the only sign of the CD. Except for postpartum complications, vaginal birth did not significantly enhance the chances of negative outcomes in pregnancies with oligohydramnios compared to vaginal delivery without oligohydramnios (9).

Of the 12,940 women who took part in the First Look Study clusters in Guatemala, Pakistan, Zambia, and the DRC and had a third-trimester ultrasound, 87 women, or 0.7%, had oligohydramnios diagnosed. Between study sites, there were differences in the prevalence of oligohydramnios, with Pakistan having the highest frequency (1.5%) and Zambia and the DRC having the lowest (0.2%). Women with oligohydramnios had a higher incidence of hemorrhage, fetal malposition, and cesarean birth compared to those without the syndrome (10).

A total of 115 cases of oligohydramnios were recorded in the study at the Nepal Police Hospital in Maharajgunj, Kathmandu, Nepa, representing an incidence of 2.4 percent. 92 of the women were full-term, making the incidence of term oligohydramnios 2%. 92 cases were involved, 77 (83.6%) required an emergency cesarean section, and 15 (16.3%) were delivered vaginally. The women were between the ages of 18 and 39, with a mean age of 25.43 ± 4.11 years. The majority of patients, 31, were aged 20 to 29 (82.6%) (11).

According to a study conducted at the Gandaki Medical College Teaching Hospital (GMCTH), Pokhara, Nepal, 60 patients who reached 37 weeks of pregnancy with an AFI of less than 5 cm and who matched the inclusion criteria were assigned to the oligohydramnios group over the course of a year. After matching the age group and parity, these patients were compared to 60 patients in the no-oligohydramnios group (AFI 5 to 20 cm). It was shown that 20% of pregnant women with oligohydramnios were in their teen years, and 80% were in the age range of 20 to 30. According to parity, 15% of women were primigravida, followed by 85% of multigravidas. In terms of delivery method, it was shown that the oligohydramnios group had a cesarean section rate of 71.7 percent and a normal delivery rate of 18.3 percent. Between the studies and the control group, there was a statistically significant difference (p < 0.001) (12).

The Maternity Teaching Hospital in Erbil, Iraq, conducted the study. Regarding parity and gestational age, there was a substantial difference between the oligohydramnios group and the reference group. Primigravids had a higher rate of oligohydramnios. Comparing the oligohydramnios group to the comparison group, the cesarean section rate was greater in the oligohydramnios group. Thirteen percent of the oligohydramnios group experienced intrauterine growth retardation. Birth weight less than 2500 g was related to oligohydramnios (21.3%) (13).

The average gestational age of all participants in the study at Charoenkrung Pracharak Hospital in Bangkok, Thailand, was 38.63 1.03 weeks. In the research and control groups, the mean AFI was 3.72 1.21 cm and 10.73 2.96 cm, respectively. Isolated oligohydramnios (study group) was linked to a greater rate in nulliparous women than in the control group (46.4 percent vs. 37.4 percent, p = 0.014). When compared to the control group, the study group had a greater incidence of primary cesarean sections (30.6 percent vs. 12.3 percent, p 0.001). When compared to the control group, the study group's greater rate of cesarean sections was justified by unsatisfactory fetal heart rate status (14.7 percent vs 2.6 percent, p = 0.001) and unsuccessful medical induction (8 percent vs 1.2 percent, p = 0.001) (14).

At the Indira Gandhi Institute of Medical Sciences in Sheikhpura, Patna, India, maternal age on average is 26.1. In our study, primipara (64.4 percent) had a higher incidence of oligohydramnios. Additionally, surgical morbidity was higher in primipara (51.7 percent). It was idiopathic, the most typical cause of oligohydramnios (44.44 percent). Operative morbidity in

non-reassuring FHR was much higher (80%) than in reassuring FHR (32 percent). A doppler research revealed that fetoplacental insufficiency affected 7 individuals (7.78%) of the population (15).

Srinagar's Sher-i-Kashmir Institute of Medical Sciences (SKIMS) study, in terms of maternal age, parity, and mean gestational age, the two groups were comparable. 68.49 percent vs. 21.8 percent, p=0.008, nonreassuring fetal heart rate (45.20 percent vs. 13.2 percent, p=0.001), cesarean section for fetal distress (51.61 percent vs. 28.47 percent, p=0.001), and meconium-stained amniotic fluid (32.2 percent vs. 21.6 percent, p=0.008) were all associated with isolated oligohydramnios (16)

According to a study conducted at the Government Mohan Kumaramangalam Medical College and Hospital in Salem, Tamil Nadu, India, among the 92 women that were enrolled, 17.04 percent (n=92) had oligohydramnios, and 62 percent (n=57) were primigravida. The cesarean section rate among the women with oligohydramnios was 56.5% (n=52), with fetal distress accounting for 44.2% (n=23) and IUGR for 34.6% (n=18) of the common reasons for LSCS. Oligohydramnios pregnancies were more likely to result in postponed births (28.3%), pregnancyinduced hypertension (10.9%), and gestational diabetes (8.7%%) (17).

There were 35,999 women in the twelve investigations, 2,414 (6.7%) of whom had isolated oligohydramnios, and 33,585 (93.29%) of whom had a normal amniotic fluid index. Cesarean sections and labor induction rates were substantially higher in patients with isolated oligohydramnios (odds ratio (OR) 7.56, confidence interval (CI) 4.58-12.48). (OR 2.07, CI 1.77-2.41). There were no significant differences in any maternal or newborn outcomes between expectant management and induction of labor in the one randomized trial that compared the two (18).

In this particular study, which was conducted at the specialized hospital of Gondar University in northwest Ethiopia, the prevalence of oligohydramnios in the third trimester of pregnancy was 2.36 percent (as the total number of deliveries in the study period was 14,382). The average age of the 133 study participants (45.1%) was 25, whereas the minimum and maximum age ranges were 18 and 40 years, respectively. The majority of the study participants, 226 (76.6%), were

from the town of Gondar. In 237 (80.2 percent) of the instances, a cesarean section was performed; the most common reason for doing so was severe oligohydramnios (C/S might be decided for the mere presence of severe oligohydramnios, for NRFHRP while undergoing oligohydramnios induction, or for the presence of a prior c/s scar or malpresentation that prevents oligohydramnios cases from being induced in our setup). Women with a history of hypertension were approximately three times more likely to experience severe oligohydramnios (AOR= 3.22, 95 percent CI (1.24-8.36)) and abortions (AOR=3.42(1.26-9.23)). The likelihood of developing severe oligohydramnios increased by one unit for every additional week of gestation (AOR= 1.58, 95 percent CI (1.16-2.17)). Women who received ANC follow-ups at private clinics had a 74 percent decreased risk of developing severe oligohydramnios (AOR= 0.26, 95 percent CI (0.10-0.68)) (8).

Fetal outcomes of oligohydramnios

A study done in Karnataka, India, found that 47 instances (19.8%) of all patients underwent NICU admission. Of the infants delivered, 144 (60.75%) had birth weights of more than 2.5 kg. APGAR 7 at 1-minute babies were observed in 36 cases (15.15 percent). There were 70 cases (29.5%) of reported meconium-contaminated alcohol (2).

At Nepal Police Hospital, Maharajgunj, Kathmandu, Nepal, six infants were brought to the Neonatal Intensive Care Unit, 14 (15.2%) babies were born with low birth weights of less than 2.5 kg, and the meconium-stained liquid was found in 12 (13%) of the oligohydramnios cases. At 1 minute and 5 minutes, 13 (14.13%) and 3 (3.26%) cases, respectively, had an APGAR score of less than 7, and one of them passed away from meconium aspiration syndrome (11).

According to research conducted at Gandaki Medical College Teaching Hospital (GMCTH), Pokhara, Nepal, low Apgar scores in oligohydramnios (18.3 percent vs. 3.3 percent) compared to no-oligohydramnios were statistically significant for newborn outcomes. Both the study group and the control group in the current study experienced no newborn deaths. When compared to the no-oligohydramnios group, NICU admission was shown to be significantly greater in the oligohydramnios group (P = 0.013) (12). According to the study conducted at Charoenkrung Pracharak Hospital in Bangkok, Thailand, birth asphyxia (4 percent vs 1.4 percent, p = 0.024), admission to a neonatal intensive care unit (5.6 percent vs 0.4 percent, p 0.001), and admission of a sick newborn (21 percent vs 13.1 percent, p = 0.005) were all significantly more common in pregnant women with isolated oligohydramnios (14).

Srinagar's Sher-i-Kashmir Institute of Medical Sciences (SKIMS) study, Regarding the Apgar score at 1 minute, NICU hospitalizations, and stillbirths, there was no statistically significant difference between the two groups (16).

According to a study conducted at the Government Mohan Kumaramangalam Medical College and Hospital in Salem, Tamil Nadu, India, it was also linked to a greater frequency of low birth weight (27.2%), NICU admissions (32.6%), congenital malformations (3.3%), and fetal fatalities (5.4%) (17).

There were increased rates of an Apgar score of 7 at 1 and 5 minutes (OR 1.53, CI 1.03-2.26, and OR 2.01, CI 1.3-3.09, respectively) and admission to the neonatal intensive care unit in the 12 studies with 35,999 women (OR 1.47, CI 1.17-1.84). No discernible variations existed between meconium-stained amniotic fluid and cord pH 7.1 (18).

2.1 CONCEPTUAL FRAMEWORK



Figure 1. Conceptual framework of maternal and perinatal outcomes between oligohydramnios and normal amniotic fluid in term singleton pregnancy.

CHAPTER THREE – OBJECTIVE

3.1 GENERAL OBJECTIVE

✓ To compare the maternal and perinatal outcomes among women with oligohydramnios and normal amniotic fluid in term singleton pregnancy from March. 2022 to Oct. 2022 in the department of obstetrics and gynecology at Jimma Medical Center, Southwest Ethiopia.

3.2 SPECIFIC OBJECTIVES

- 1. To identify the prevalence of oligohydramnios.
- 2. To compare Maternal outcomes between oligohydramnios and normal amniotic fluid in term singleton pregnancy.
- 3. To compare perinatal outcomes between oligohydramnios and normal amniotic fluid in term singleton pregnancy.
- 4. To identify predictors of perinatal and maternal outcomes of oligohydramnios

CHAPTER FOUR -METHODOLOGY

4.1 Study area and Period

The study was carried out at Jimma Medical Center (JMC), one of the oldest public hospitals founded in 1937 as Jimma Hospital, later renamed Jimma University Specialized Hospital (JUSH), and now named JMC. JMC is the only teaching and referral hospital in the southwestern region of the nation, located in Southwest Ethiopia 354 kilometers from Addis Ababa. With a very large catchment population of roughly 15 million people in southwest Ethiopia, it is a referral hospital that serves about 9,000 inpatient and 80,000 outpatient attendances annually.

The hospital has a total of 659 beds, of which 52 are in the maternity ward, and offers practically all of the major forms of medical care. There are 11 beds on the first level and 5 in the second stage. Midwives, medical interns, resident obstetricians, gynecologists, and obstetrics and gynecology consultants oversee the labor and delivery rooms. The hospital is a referral facility for the southwest region of the nation, and the majority of laboring women are from rural areas. The research was carried out between March 2022 and October 2022 G.C.

4.2 Study design

The research was done using a hospital-based prospective cohort study design. 270 term pregnant mothers were admitted to the labor ward and 90 mothers with Amniotic fluid Single deepest pocket (SDP) <2cm identified as oligohydramnios as exposed and 180 mothers with amniotic fluid Single deepest pocket \geq 2 and <8cm and non-exposed group. Perinatal outcomes were observed at admission, throughout intrapartum, and till 7 days following delivery. Telephone-based information was used to complete data after discharge to one week postpartum

4.3 Source population

All pregnant mothers were admitted for labor and delivery at JMC's obstetric and Gynecologic department from March to Oct. 2022.

4.4 Study population

Two hundred seventy (270) pregnant mothers were admitted for labor and delivery at JMC's obstetric and Gynecologic department.

4.4.1 Inclusion criteria

Exposed

- Amniotic fluid index ≤ 5.0 cm or Single deepest pocket < 2 for the women with oligohydramnios
- Singleton fetus despite their presentation
- No lethal congenital anomalies
- Alive baby
- Gestational Age between \geq 37 weeks and <42 weeks
- High-risk pregnancy
- Intact Membrane

Non Exposed

- Amniotic fluid index > 5.0 cm and <25 cm or Single deepest pocket ≥ 2 and <8cm.
- Singleton fetus despite their presentation and mode of delivery
- No lethal congenital anomalies
- Alive baby
- Gestational Age between \geq 37 weeks and <42 weeks
- Intact Membrane

4.4.2 Exclusion criteria

- Gestational Age between <37 weeks and ≥42 weeks
- IUFD
- Lethal congenital anomalies
- Ruptured membranes
- Multiple gestations

4.5 Sample size determination

The sample size was determined by OpenEpi, version 3.01 software calculation. We used the proportion of perinatal and maternal outcomes of oligohydramnios in third-trimester pregnancy done at Felegehiwot Comprehensive Specialized Hospital and Tibebe Ghion Specialized Hospital, Bahir Dar, Northwest Ethiopia, and the Proportion of NICU admission which is found to be significant, 0.27 and 0.1 was used for Exposed and non exposed respectively, The minimum required for the study was 249.

Two-sided significance level(1-alpha): 95

Power (1-beta, % chance of detecting): 95

The ratio of sample size, Unexposed/Exposed:2

Percent of Unexposed with Outcome: 10

Percent of Exposed with Outcome: 27

Odds Ratio: 3.3

Risk/Prevalence Ratio: 2.7

Risk/Prevalence difference: 17

	Kelsey	Fleiss	Fleiss with CC
Sample Size - Exposed	90	98	107
Sample Size-Nonexposed	180	196	213
Total sample size:	270	294	320

4.6 Sampling technique

All singleton deliveries with oligohydramnios at JMC from March. 2022 to Oct. 2022 G.C. were included in the study. The cases were interviewed by mothers and physicians, recorded from patients' cards and maternal and fetal outcomes were followed. The first Cases were selected randomly by matching their Age with the respective two Controls collected on that day or subsequent days.

4.6.1 Study variables

4.6.1.1 Dependent variable

- 1. Perinatal outcome of Oligohydramnios (NICU admission, 5th minute APGAR Score, the status of the neonate at discharge)
- The maternal outcome of Oligohydramnios (Onset of labor, Mode of delivery)

4.6.1.2 Independent variable

- Socio-Demographic factors: Age, Place of residence, education level, occupation, marital status, religion, and ethnicity.
- o Obstetric factors: Onset of labor, Mode of delivery
- o Maternal Factors: Hypertensive disorders, Medication
- o Fetal Factors: Gestational age, sex, weight

4.7 Data collection

4.7.1 Data collection instrument

Data was collected using Kobo Toolbox. A Structured questionnaire was prepared in English and translated into the local language during the interview. The questionnaire consisted of four sections: i. socio-demographic characteristics of mothers (9 questions), ii. obstetrics history and risk factors (7 questions), iii. Maternal outcome (15 questions), and v. perinatal outcomes (7 questions).

4.7.2 Data collector

Data was collected by medical interns and residents of obstetrics and gynecology by using Kobo Toolbox. One hour of training was given to data collectors about the data collection instrument and how to collect the data. The data collection process and the completeness of collected data were checked daily by the supervisor.

4.7.3 Data collection procedure

Data was collected from the participant's medical records (Maternal outcome and perinatal outcomes) and from a face-to-face interview with the patient (socio-demographic characteristics of mothers and obstetrics history and risk factors), and the most senior resident who participated in the management. The mothers and their newborns were followed through their whole stay in the hospital and until seven days after delivery. Mothers were followed after discharge on phone for Perinatal outcome until 7 days.

4.8 Data processing and analysis

Data was transferred by downloading (Xls and SPPS format) from the Kobotool box to SPSS Version 26 and statistical analysis was performed. Proportions were used for categorical variables and mean with respective measures of dispersion for numerical variables.

The X^2 and odds ratio (OR), with a 95% Confidence Interval (CI) used to measure the strength of association between oligohydramnios and background variables (sociodemographic, and reproductive health characteristics) and perinatal outcomes with categorical variables. ANOVA and independent t-test for multiple comparisons of oligohydramnios and non-oligohydramnions groups based on their adverse pregnancy outcomes (LBW, APGAR score, and NICU admission). Logistic regression analysis was performed to determine the predictors of oligohydramnios and control for the confounders. The 95% CI and p value of less than 0.05 were considered to determine the level of statistical significance.

4.9 Data quality control

One hour of training was given to the data collectors on how to collect data. The data collection instrument was adapted from the Maternal and Perinatal Death Surveillance and Response Technical Guideline of Ethiopia and the questionnaire was field tested and approved by the Federal Ministry of Health to be used at any hospital or health center in Ethiopia. The questionnaire was pretested while collecting data in the labor and maternity ward then the subsequent modification was done. The collected data were reviewed and checked for completeness daily by the investigator. To avoid selection bias of nonexposed, Data from exposed and nonexposed were collected by different Personnel.

4.10 Measurement

Amniotic fluid was measured by using transabdominal ultrasonography. The single deepest vertical pocket (SDVP) was taken; which is the vertical dimension in centimeters of the largest pocket of amniotic fluid not containing fetal extremities or umbilical cord and the horizontal component of the vertical dimension must be at least 1cm. Those measures <2cm and ≥ 2 and <8cm were taken as oligohydramnios and normal amniotic fluid respectively.

4.11 Operational definition

- Apgar score: This is an assessment of the newborn condition right after birth, at 1, and 5 minutes, by evaluating the 5 indicators: color, heart rate, Grimace (response to stimuli), Activity (Tone), and Respiration (breathing rate). (Favorable fetal outcome neonates with 5th minute Apgar score > 7 with and without complication & Unfavorable fetal outcome stillbirth, neonates with 5th minutes APGAR score < 7, ENND, and those admitted to NICU with complications like PNA, EONS, and MAS)
- 2. Asphyxia: A condition in which insufficient or no oxygen and carbon dioxide are exchanged on a ventilator basis or APGAR less than 7 at 1st and 5th minutes.
- 3. ENND neonatal death within 7 days of life
- 4. Neonatal death: Death of the newborn in the first month of life
- 5. Perinatal mortality death after 28 weeks of gestation plus early neonatal death

- 6. Fetal-growth restriction neonates whose weights are below the 10th percentile for their gestational age
- NICU admission Neonate admitted to NICU immediately after delivery and within 7 days after delivery
- 8. High-risk pregnancy- when pregnancy is complicated by factors or factors that adversely affect the maternal, perinatal, or both outcomes.
- Adverse Perinatal outcome- if at least one outcome is presented (NICU admission and 5th minute APGAR Score<7)

4.12 Data Ethical Assurance

The study was reviewed and approved by JU, the health institute's institutional review board (IRB). Written consent was taken from respondents and confidentiality of information collected from each participant was maintained.

4.13 Utilization and Dissemination of Results

The proposal and final result of this study will be submitted to the department of obstetrics and gynecology, college of health science and the final result from the study will be submitted to the CBE office, JU college of public health and medical science in the form of a written report and presented for concerned bodies and finally submitted to a peer-reviewed journal for publications

5. Results

5.1 Socio-Demographic Characteristics of study participants

The number of deliveries that took place from March. 2022 to Oct. 2022 in Jimma Medical Center were 4127 deliveries. The deliveries complicated with oligohydramnios were 109 (90 +19) and the prevalence in this particular study is 2.64%. 270 women (90 exposed group and 180 nonexposed groups) participated in the study with a response rate of 100%. The exposed mean age was 25.13 (SD of 4.277) with an age range of 18 to 38 years; the nonexposed mean age of 25.41 (SD of 4.683) with an age range of 17 to 40 years. Of the 270 participants, the majority were from the urban 185 (68.5%), Oromo 184 (68.1%), married 263 (97.4%), Muslim 129 (47.8%), Level of education from grade 9 to grade 12, 115 (42.6%), and housewife 174 (64.4%) demographics.

Variable		Exposed N (90)	Nonexposed N	P value	
		(%)	(180) (%)		
Age	<20	4 (4.4)	19 (10.6)	.045	
	20-34	73 (81.1)	149 (82.8)		
	≥35	13 (14.4)	12 (6.7)		
Residence	Rural	33 (36.7).	52 (28.9)	.196	
	Urban	57 (63.3)	128 (71.1)		
Ethnicity	Oromo	59 (65.6)	125(69.4)	.768	
	Amhara	23 (25.6)	39 (21.7)		
	Others	8 (8.9)	16 (8.9		
Marital Status	Married	87 (96.7)	176 (97.8)	.591	
	Others	3 (3.3)	4 (2.2)		
Religion	Protestant	18 (20)	32 (17.8)	.161	
	Orthodox	32 (35.6)	44 (24.4)		

Table 5.1: Socio-Demographic Characteristics of women who were admitted to Jimma Medical Center, South West Ethiopia, from March. 2022 to Oct. 2022.

	Muslim	37 (41.1)	92 (51.1)	
	Others	3 (3.3)	12 (6.7)	
Level of	Can`t read or write	8 (8.9)	1(0.6)	.004
Education	No formal education but read and write	4 (4.4)	7 (3.9)	
	Grade 1-8	18 (20)	63 (35)	
	Grade 9-12	35 (38.9)	80 (44.4)	
	College and above	25 (27.8)	29 (16.1)	
Occupation	Government Employer	19 (21.1)	19 (10.6)	.059
	House Wife	55 (61.1)	119 (66.1)	
	Other	16 (17.8)	42 (23.3)	

5.2 The Obstetric history of study participants

Forty-six (51.1%), out of the exposed (90) pregnant participants in our study, and 122 (67.8%) of the 180 nonexposed groups were multigravida (≥ 2). In 31 (34.4%) of the exposed group, their gestational age is 39-40+6 weeks. 88 (97.8%) of the exposed group and 179 (99.4%) of the nonexposed group, had ANC follow-up. 40 (44.4%) of the exposed group had obstetric risk, with 13 (14.4%) of them having PE/Eclampsia, 11 (12.2%) having abnormal placentation, and 16 (17.8%) having IUGR.

Table 5.2: Comparison of obstetric history between exposed and nonexposed of women who were admitted to Jimma Medical Center, South West Ethiopia, from March. 2022 to Oct. 2022.

Variable		Exposed N (90) (%)	Nonexposed N	P Value
			(180) (%)	
Reproductive	G1	44 (48.9)	58 (32.2)	.030
History	G2 - G4	29 (32.2)	76 (42.2)	
	≥G5	17 (18.9)	46 (25.6)	
GA (Weeks)	37 - 38+6	20 (22.2)	60 (33.3)	.078
	39 - 40+6	31 (34.4)	67 (37.2)	
	41 - 41+6	20 (22.2)	22 (12.2)	
	Unknown (Ballard 38-	19 (21.1)	31 (17.2)	
	40)			
ANC Follow up	Yes	88 (97.8)	179 (99.4)	.255
	No	2(2.2)	1(0.6)	
Antepartum Risk	PE/Eclampsia	13 (14.4)	19 (10.6)	.001
Factors	Abnormal	11 (12.2)	6 (3.3)	
	Placentation			
	IUGR	16 (17.8)	13 (7.2)	
	No Problem	50 (55.6)	142 (78.9)	

5.3 Maternal Outcome

Thirty-seven (41.1%) of the exposed had spontaneous labor, 42 (46.7%) induced labor, and 11 (12.2%) had an elective cesarian section with p value of <.001. A caesarian delivery was used for the majority of the delivery 48 (53.3%) with an indication of NRFHRP 32 (35.6%) with p value of .001, while spontaneous vaginal birth was 32 (35.6%), and operative vaginal birth for 10 (11.1%), with an indication of NRFHRP 7(8.4%). All women were discharged with no complications.

Variable		Exposed N	Nonexposed	X ²	OR (95% CI)	P Value
		(90) (%)	N (180) (%)			
Age	<20	4 (4.4)	19 (10.6)	6.571	1	.616
	20-34	73 (81.1)	149 (82.8)		.751 (.148-3.797)	
	≥35	13 (14.4)	12 (6.7)		.441(.064-3.04)	
GA	37 - 38+6	20 (22.2)	60 (33.3)	6.975	1	.130
(Weeks)	39 - 40+6	31 (34.4)	67 (37.2)		.632(.254-1.58)	-
	41 - 41+6	20 (22.2)	22 (12.2)		.405 (.139-1.186)	_
	Unknown	19 (21.1)	31 (17.2)		.32(.116883)	
	(Ballard 38-40)					
Onset of	Spontaneous	37 (41.1)	160 (88.9)	70.051	1	< 0.001
Labor	Induced	42 (46.7)	14 (7.8)		.079(.037168)	-
	Elective	11 (12.2)	6 (3.3)		.477(.149-1.525)	_
	cesarian section					
Mode of	Vaginal	32 (35.6)	134 (74.4)	45.252	1	< 0.001
delivery	Delivery					
	Operative	10 (11.1)	18 (10)		.683(.244-1.912)	
	Vaginal					
	Delivery					
	Cesarean	48 (53.3)	28 (15.6)		.150(.072315)	
	Delivery					
Indication	NRFHRP	8 (8.9)	11 (6.1)	1.416	.341(.127918)	.183
for	Shorten SSOL	1 (1.1)	5(2.8)		1.240(.149-10.99)	1
Operative	Poor Maternal	1 (1.1)	2 (1.1)		.496(.044-5.644)	
Vaginal	Effort					
delivery	Not applied	80 (88.9)	162 (90)		1	_
Indication	NRFHRP	32 (35.6)	25 (13.9)	48.142	1.728(.423-7.054)	< 0.001
for C/S	CPD	2 (2.2)	0 (0)		0	-

Table 5.3: Comparisons of maternal outcome between exposed and nonexposed of women who were admitted to Jimma Medical Center, South West Ethiopia, from March. 2022 to Oct. 2022.

Malpresentation	10 (11.1)	0 (0)	0
Others	4 (4.4)	8 (4.4)	1

5.4 Perinatal Outcome

From those mothers who participated in the study during the study period, 19 (10.6%) of mothers with normal AF and 26 (28.9%) from oligohydramnios had Perinatal outcome with p value of .001. During the study period there is no intrapartum fetal death due to oligohydramnios.

In the exposed groups, 49 (54.4%) of the newborns were male, while the majority of the 101 (56.1%) newborns in the nonexposed group were female. Neonatal born who had low birth weight (<2500g) in the exposed group were 11 (12.2%) and 4 (2.2%) in nonexposed group with p value of .007. The 5th minute APGAR score was < 7, 1 (1.1%) in exposed and 0(0) in the nonexposed group. Only 7 (7.8%) in exposed and 17 (9.4%) in the nonexposed group, the newborns were admitted to the NICU, and of those admitted, 2 (2.2%) in the case and 1(0.6%) in the control group complicated by ENND

Table 5.4: Comparisons of Perinatal Outcome between exposed and nonexposed who were managed in Jimma Medical Center, South West Ethiopia,2022. Using Independent T test.

Variable		Exposed N (90)	Nonexposed N (180)	Mean Difference (95% CI)	P Value
		(%)	(%)		
Sex of Neonate	Male	49 (54.4)	79 (43.9)	106 (-232021)	.102
	Female	41 (45.6)	101 (56.1)	106 (233022)	
Birth weight	< 2500g	11 (12.2)	4 (2.2)	100 (157043)	.007
	≥ 2500g	79 (87.8)	176 (97.8)	100 (172028)	
APGAR Score at	<7	1 (1.1)	0 (0)	011 (.027004)	.320
5 th min	≥7	89 (98.9)	180 (100)	011 (033011)	-
NICU admission	Yes	7 (7.8)	17 (9.4)	.017 (056089)	.652
	No	83 (92.2)	163 (90.6)	.017 (054087)	-
Neonatal status at	Improved	5 (71.4)	16 (94.1)	.067 (-143277)	.533
discharge	ENND	2 (28.6)	1 (5.9)	.067 (133267)	-
Perinatal Outcome	Yes	26 (28.9)	19 (10.6)	183 (276091)	.001
	No	64 (71.1)	161 (89.4)	183 (289078)	

6. Discussion

The primary objective of antenatal screening is to detect any conditions which can lead to highrisk pregnancy. An ultrasound examination during that period is a sensitive and reliable method of assessing the amniotic fluid and detecting oligohydramnios or polyhydramnios. Assessment of AFV during the antenatal period is considered a helpful tool in determining who is at risk for the potentially adverse perinatal outcome. Therefore, this study aimed to evaluate how oligohydramnios affected the outcomes for the mother and fetus.

The prevalence of oligohydramnios in this particular study which is within 8 months is 2.64%, which is higher than the study done in Pakistan (1.5%) and Zambia and the DRC have the lowest (0.2%) (10), the study conducted at the specialized hospital of Gondar University in northwest Ethiopia (2.36%), which is probably due to difference in the study design and duration of the study period and since this study is done on referral hospital and there is high patient flow (8).

The mean age of the exposed participants was 25.13 (SD of 4.277) with an age range of 18 to 38 years; the nonexposed mean age of 25.41 (SD of 4.683) with an age range of 17 to 40 years which is almost comparable with a study done at the Nepal Police Hospital in Maharajgunj, Kathmandu, Nepa, (11), a study conducted at the specialized hospital of Gondar University in northwest Ethiopia (8), and higher than a study done at NIMS Medical College and Hospital, Jaipur, Rajasthan, INDIA (5).

According to our result having oligohydramnios increases the risk of being induced labor 42 (46.7%) with a p-value <0.001. This result is similar to the study done in India (3) and higher than SMS Medical College, Jaipur, Rajasthan, India (7).

These mothers have a high relative risk of delivering by a cesarean section 48 (53.3%) with a P-value of <.001, which is lower than the Chinese study (84.4 versus 54.7 percent; p.001) (9), Nepal Police Hospital in Maharajgunj, Kathmandu, Nepa, (77 (83.6%)) (11), Nepal (71.7%) (12), Iraq (13), India 56.5% (n=52), (17), (65% of cases and 10% of controls) in the study by Mathuriya G et al (4) but higher than Thailand (30.6 percent vs. 12.3 percent, p 0.001) (14), (SKIMS) study (51.61 percent vs. 28.47 percent, p=0.001) (16), Agarwal S et al., who found that patients with oligohydramnios had a Cesarean delivery rate as high as 35.3% (3). Such variations

could be attributed to geographic locations and study periods. In order to combat the negative impact on the perinatal outcome, CS was generally the best option.

In the current study, fetal distress was the most frequent cause of C-sections 32 (35.6% in the exposed group) with a p-value of <0.001, which is lower than in Surabhi et alstudy, which indicated that fetal distress was the most common reason for LSCS (60.72%), followed by severe oligohydramnios in 17.86% of patients (5) and (SKIMS) study, nonreassuring fetal heart rate (45.20 percent vs. 13.2 percent, p=0.001), (16). Cord compression is most likely the cause here due to a volume reduction in amniotic fluid

In our study, Compared to the nonexposed, Significant associations were found in birth weight <2500g among women with oligohydramnios 11 (12.2%) compared to the control group 4 (2.2%) with a P-value of .007. It's lower than a study done in Karnataka, India 144 (60.75%) had birth weights more than 2.5 kg (2), At Nepal Police Hospital 14 (15.2%) (11), India (27.2%), (17).

We observed that perinatal outcome in exposed 26(28.9%) and 19(10.6%)in nonexposed is significant with P value of .001.

7. Conclusion

- The prevalence of oligohydramnios is higher than in studies done in Pakistan, Zambia, DRC, and Gondar, Ethiopia.
- Oligohydramnios significantly impacts the onset of labor and mode of delivery.
- Having oligohydramnios has an adverse perinatal outcome.

8. Recommendation

- Further study is needed to identify what increases adverse maternal and perinatal outcomes related to oligohydramnios.
- A health information leaflet about oligohydramnios should be created and given to pregnant mothers.
- Having a meeting with the health professional staff at the antenatal clinic to encourage them to inform expectant mothers about oligohydramnios and associated maternal and fetal complications.

9. Strength and limitation

- Gestational age is not known so we used the Ballard score
- The study identifies as oligohydramnios is strongly associated with adverse pregnancy outcomes but not their cause-effect relationship is not studied in this study.
- In addition to a short-term observational study, its generalizability is for short-term perinatal outcomes of oligohydramnios during Term pregnancy and not for the remaining trimesters, so a long-term follow-up study that incorporates all trimesters will be needed to understand their cause-effect relationship including long-term neonatal outcomes.

Annex I

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Annex II

Questionnaires

Questionnaire for the study of maternal and perinatal outcomes between oligohydramnios and normal amniotic fluid in term singleton pregnancy in JMC, southwest Ethiopia, a matched casecontrol study

Information sheet and mothers Consent form (English)

Information sheet: Good morning. / Good afternoon. My name is Dr.Darartu Fikre. I am 4th (final) year obstetrics and gynecology resident at Jimma University. I am conducting a study on maternal and perinatal outcomes between oligohydramnios and normal amniotic fluid in term singleton pregnancy in JMC for my partial fulfillment of the requirements for the master's degree in Obstetrics and Gynecology. You are chosen to participate in the study. We need to collect data about socio-demography and economic information from you. The chart of the deceased will be reviewed to get data about your obstetric characteristics and pregnancy outcome. I assure you that all your answers will be kept strictly secret. I will not keep a record of your name or address. You have the right to stop the interview at any time or skip any questions you don't want to answer. Your participation is completely voluntary but your experiences could be very helpful to design a better action plan to mitigate Maternal and Fetal Outcomes occurring from the same scenario in the future.

If you agree to participate in the study, the interview will take about 30 minutes to complete. Do you have any questions?

Consent form

Do you agree to be interviewed?

Yes No

May I begin the interview now?

Yes No

To be signed by the interviewer: I certify that I have read the above consent procedure to the participant.

Signed: _____

I Socio-demographic Characteristics

No.	Question	Answers	Remark
101	Card no.		
102	Age (In Years)		
103	Place of Residency	Rural	
		Urban	
104	Ethnicity	Oromo	
		Amhara	
		keffa	
		Tigire	
		Others (Mention)	
105	Marital status	Single	
		Married	
		Cohabited	
		Divorced	
		Separated	
		Widowed	
106	Religion	Orthodox	
		Muslim	
		catholic	
		Protestant	
		Others	
107	Level of education	Can`t read and write	
		No formal education, but can read	
		and write	
		Grade 1-8	
		Grade 9-12	
		College & above	
108	Occupation	Gov`t employer	

Merchant	
House wife	
Farmer	
Student	
Others (mention)	

II Obstetric history and Risk Factors

201	Reproductive History?	Gravidity
		Parity
		Abortion
		Ectopic
		GTD
202	GA	In weeks
		Unknown (Ballard)
203	ANC Follow up	Yes
		No
204	If Yes to Q.203, where is the ANC	Health post
	follow up?	Health center
		Public Hospital
		Private Hospital
		Private Clinic
205	If Yes to Q.203, How many visit?	
206	If No to Q.203, Why?	
207	Antenatal/ intranatal problems/risks	Pre eclampsia /
	(Tick ALL that apply	eclampsia
		Prolonged pregnancy
		IUGR
		Other (specify)

III Maternal Outcome

301	Level of Amniotic Fluid	SDP	
		AFI	
302	Onset of Labor ?	Spontaneous	
		Induced	
		No labor (Elective C/S)	
303	Duration of labor	hour	
304	Mode of delivery	Spontaneous vaginal delivery (SVD)	
		Operative vaginal delivery (vacuum or	
		forceps)	
		Operative Abdominal delivery (caesarean	
		section)	
305	If mode of delivery is Operative		
	vaginal delivery, what is the		
	Indication?		
306	If mode of delivery is Operative		
	Abdominal delivery (caesarean		
	section), what is the Indication?		
307	Is there any Post Operative or	Yes	
	/and Postpartum complications?	No	
308	If yes to above question what is	s Postpartum Infection and sepsis	
	it?	Wound dehiscence	
		Anemia	
		Other and specify	
309	Duration of stay at Hospital		
	before delivery		
	Specify		
	Specify		
310	Total stay at Hospital?		

	Specify		
311	Status of the mother on discharge?	Improved others	

IV Perinatal

401	Neonatal	Sex	М	
	Outcome		F	
		Weight		
		Status	Alive	
			ENND	
		Apgar		
		score at 1 st		
		and 5 th		
		minute		
403	If alive, Any need for NICU admission?		Yes	
			No	
404	If yes to the above		Prematurity with respiratory problem	
	question,	what reason	Neonatal sepsis	
	for admission to NICU?		Asphyxia	
			Meconium Aspiration Syndrome	
			Hyperbilirubinemia	
			Others and specify	
405	Status of the New born finally		Discharged improved	
			ENND	
			Alive till 7 th day	
406	If comp	licated by	Within 24 hr	

	ENND, when was the	24 - 72 hr	
	time of death respective	$72hr - 7^{th} day$	
	to age?		
407	If complicated by	Respiratory	
	ENND, what is the	Multi organ failure	
	immediate cause of	Lethal congenital malformation	
	death?	Others (mention)	