PROM outcome

by Tazebachew Wudie

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Perinatal and Maternal Outcome of Term Prelabor Rupture of Membrane (PROM) at Three Teaching Hospitals in Addis Ababa

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Abbreviations and Acronyms

ANC_ Antenatal care

AOR_ Adjusted Odds Ratio

BLH_Black Lion Hospital (can be used as TASH interchangeably)

BMI_Body Mass Index

DC_Data Collectors

CS_Cesarean Section or SD for cesarean delivery

EDHS_Ethiopian Demographic Health Survey

EONS_Early Onset Neonatal Sepsis

GMH_Ghandi Memorial Hospital

IAI_Intra amnio6tic Infection

IUFD_ Intrauterine Fetal Death

LMIC_Low and Middle Income Countries

MAS_Meconium Aspiration Syndrome

NICU_Neonatal Intensive Care Unit

PNO_Perinatal Outcome

OPD-Out Patient Department

PROM_Prelabor or Premature Rupture of Membrane

PPH_Post partum haemorrhage

PI_Principal Investigator

TASH_Tikur Anbessa Specialized Hospital can be used as BLH or TAH(Tikur Anbessa Hospital)

WHO_World Health Organization

ZMH_Zewuditu Memorial Hospital

Abstract

Background: About 8% of pregnancies are complicated by membrane rupture at term without spontaneous labor. Based on the various risk factor consideration, different clinical guidelines are employed in different national medical schools. The diagnosis, treatment, and results of term PROM as practices in the three hospitals of the Medical School in Addis Ababa are the main topics of this proposal.

Objective: To evaluate the maternal and perinatal outcomes of term PROM in women who delivered in Addis Ababa's three Medical School facilities.

Method and materials: From December 1, 2019, to May 31, 2020 GC, 304 women with term PROM who gave birth at Addis Ababa Three Government Teaching Hospitals (TASH, ZMH, and GMH) participated in a hospital-based prospective cross-sectional study. The study participants were chosen using the convenience sample technique. After obtaining consent, a structured and pretested questionnaire was utilized to gather medical and sociodemographic information through interviews and clinical chart reviews. SPSS 25 was used to enter and analyze the data. Study participants were described using descriptive statistics such as frequency and measure of central tendency. After binary analysis, logistic regression was applied to components that were strongly linked ($\alpha < 0.05$).

Results: Among 300 term PROM respondents ,2.3% (n=7) developed chorioamnionitis. And 14% (n=43) and 11%(n=33) complicated with poor perinatal and maternal outcome respectively. Maternal education, gravidity and mode of delivery had significant association with poor composite perinatal outcomes. Participants without formal education and primigravid participants had 9.8 and 2.4 folds increased (AOR=9.8, 95%CI=2.31, 41.9), 2.4 and (AOR=2.4, 95%CI=1.86, 6.76) risk of poor perinatal outcome when compared to higher education & grand multipara participants respectively. Participants who delivered by C/S had 1.8 folds higher poor perinatal outcome compared to who delivered vaginally (AOR=1.8, 95%CI=1.49, 2.87).

Conclusion: Term PROM has significant maternal and perinatal outcome of 13% and 11% respectively, And mothers with no formal educational background and primigravida mothers had significant poor perinatal outcome.

Keywords: Prelabor Rupture of membrane, perinatal outcome, maternal outcome, chorioamnionitis, early onset neonatal sepsis, neonatal death, IUFD,END

1 INTRODUCTION

1.1 Statement of the Problem

Prelabour rupture of membrane (PROM) complicates approximately 5%–10% of all pregnancies, of which approximately 80% occur at term It's also linked to significant maternal and fetal morbidity and mortality[1,2].. It has been shown to be the cause of 18%–20% and 21.4% of prenatal mortalities and morbidity respectively [3,4,5]. Sepsis, asphyxia, and pulmonary hyperplasia are most common causes of fetal death associated with PROM. Delivery is earlier in women with intrauterine infection than in non-infected women, and infants born with sepsis have a mortality rate four times higher than those without sepsis [6]. Placental abruption, postpartum endometritis, and intra-amniotic infection (13–60%) are examples of maternal problems. (7,8). In developing nations, the leading causes of maternal and fetal death are identified as hypoxia, infection, hypertension, and preterm birth [2,9].

Approximately half of all maternal deaths worldwide are caused by Ethiopia and the other five nations. To lower child mortality and enhance mother health, Ethiopia has created a number of programs and initiatives. Ethiopia continues to have the highest rate of maternal deaths worldwide, nonetheless. The biggest obstacle to achieving the maternal health goal (MDG5) is this [10].
According to a study on obstetric referral reasons conducted in Addis Ababa, Ethiopia, a significant percentage of referrals from health centers to hospitals occurred, with PROM being the primary reason for referral.
Due to this, there were differences in how PROM was specifically diagnosed and managed, as well as differences in how PROM was diagnosed and managed in health facilities as a result of unclear clinical standards and a competency gap [11].

To reduce the number of fetal and maternal difficulties that are typically caused by infection, diagnosis and appropriate treatment are crucial. However, many moms arrive at health facilities late in nations like Ethiopia where they lack the requisite staff and are poorly organized.
The outcome of a pregnancy is significantly impacted by PROM. An opportunity for a suitable intervention is lost when a diagnosis is made too late. Making the correct diagnosis in order to administer the appropriate treatment can be challenging in certain circumstances, although in the majority of cases, the diagnosis does not result in more serious issues [12].
In order to reduce maternal and newborn mortality as well as to improve management and prevent complications, the result for both the mother and the fetus in PROM is crucial.
Therefore, the purpose of this study is to ascertain the PROM outcomes for both the mother and the fetus in term pregnant women who gave birth at the three teaching hospitals in Addis Ababa, Ethiopia (TAH, GMH, and ZMH).

1.2 Rationale of the study

The findings of this study will provide information on the effects of term PROM, which have a major impact on mothers and perinatal managements. Hospital administrators, ministry of health

planners, and the management of term PROM in the three teaching hospitals will use this information to develop strategies for future research and implementation.

The results of this study will serve as the foundation and input for our setup's term PROM ma The findings will also help various maternity care-related non-governmental organizations (NGOs) create long-term intervention plans that will improve the quality of care for mothers. One of the goals of the Ethiopian Federal Government is to improve maternity and child care. Therefore, stakeholders will gain valuable insight from the study's findings.

This will therefore contribute to raising the standard of care for mothers generally. Furthermore, because there is a dearth of research on the subject in the nation, the data produced by the study will serve as a springboard for additional research and a source of information for other academics looking to carry out comparable studies in other regions of Ethiopia.

2 LITERATURE REVIEW

Both patients and physicians are confused by premature rupture of the fetal membranes (PROM), which is the rupture of the amniotic membranes with the leaking of amniotic fluid prior to the start of labor. Serious maternal and neonatal morbidity and mortality may result from it. When the amniotic membranes burst and the amniotic fluid is released more than an hour before labor begins, this is known as premature rupture of the fetal membranes (PROM). PROM may be subdivided into term PROM (TPROM, i.e. PROM after 37 weeks of gestation) and preterm PROM (PPROM, i.e. PROM prior to 37 weeks of gestation). Prolonged PROM is any ROM that last longer, for more than 18 hours before start of labor is induced [1-3].

The epidemiology of PROM differs significantly across nations and regions. Compared to developed nations, the frequency is higher in Africa. In USA PROM complicates approximately 3 percent of preterm pregnancies,10% of term pregnancy a, 11% of preterm delivery and causes 40 - 75% neonatal deaths [2-3]. Term or preterm uterine contractions can also lead to membrane rupture resulting from increased bursting pressure due to increased intra-amniotic pressure and from “strain hardening “with repeated uterine contractions. There are a number of pathways that result in accelerated membrane weakening. Bacterial collagenases and proteases can directly cause fetal membrane tissue weakening.
Histological investigation in the context of preterm birth has often shown acute inflammation and bacterial contamination along the choriodecidual interface, and amniotic fluid cultures during PROM are often positive (25–3 %) [4,5,7]. Poor people are most likely to have it (72%), followed by middle-class people (21%), and upper-class people (7%). Out of 100 moms, 26% had PROM that lasted less than 24 hours, and 74% had PROM that lasted more than 24 hours, according to the study. Results from 16 cases of preterm premature rupture of the membrane showed that 12% of the mothers had septicemia and 12% had chorioamnionitis.
In 27 cases of preterm premature rupture of membrane, the fetal outcome revealed that 5% of the cases had prematurity, 4% had fetal distress, 5% had cord compression, 2% had necrotizing enterocolitis, 9% had hypoxia, and 2% had pulmonary hypoplasia [2,3,6]. The majority of

women with PROM give birth within a week, and preterm PROM is linked to a short latency from membrane rupture to delivery. Latency generally rises as the gestational age at membrane rupture decreases. Ninety-three percent of women who have PROM before 34 weeks of pregnancy will give birth within a week, and 50–60% of those who receive conservative management will do so.

When PROM happens close to the limit of viability, 60% to 70% of babies are born in a week, but if conservative management is used, 1 in 5 will have a delay of four weeks or longer [7,8,13]. PROM increases the risk of perinatal infection and umbilical cord compression due to oligohydramnios, and it is linked to a short latency from membrane rupture to delivery at any gestational age. As a result, perinatal morbidity and death are significantly influenced by both term and preterm PROM. Delivering a newborn who is not infected and who is not asphyxiated reduces the chance of serious neonatal problems for term PROM. The goal of clinical management should be delivery.

Deliveries between 32 and 36 weeks gestation are typically linked to favorable infant outcomes, despite the possibility of problems, especially if the fetus has demonstrated pulmonary maturity. Delivery of the mature fetus is usually recommended, especially at 34 weeks' gestation or later, given the hazards of continuing the pregnancy and the expected short latency.
Preterm prelabour membrane rupture is probably caused by a number of factors that eventually accelerate membrane weakening, such as increased collagenase and protease activity, an imbalance in the interaction between MMPs and TIMPs, an increase in local cytokines, or other factors.
Placental abruption, intrauterine infection, and compression of the umbilical cord are the main fetal consequences of PROM. Following PROM, it's also typical to observe fetal heart rate patterns that match umbilical cord compression brought on by oligohydramnios. After membrane rupture, umbilical cord prolapse may happen, particularly in cases of fetal malpresentation, which is more frequent in preterm pregnancies. Clinical assessment, which combines history, clinical examination, and laboratory evaluation, can confirm the diagnosis of PROM in over 90% of cases. Urine leakage, increased vaginal discharge with cervical dilatation or membrane prolapse, cervical infection, mucus plug passage, semen or vaginal douching, and other possibly confusing circumstances might also be taken into account. factors that raise intrauterine pressure, such as polyhydramnios [14–18].
A sterile speculum examination should be performed to provide confirmatory evidence of membrane rupture and to inspect for cervicitis and for umbilical cord or fetal prolapse, to assess cervical dilatation and effacement, and to obtain cultures.

Digital cervical examination should be avoided except imminent delivery is anticipated. If the diagnosis is not confirmed on initial inspection, the pH of the vaginal side walls or pooled vaginal fluid can be evaluated using Nitrazine paper, which turns blue at a pH above 6.0 to 6.5. If further clarification is needed, microscopic inspection for the presence of arborized crystals (i.e., ferning) can be performed in an air-dried sample collected from the vaginal side walls or pooled vaginal fluid [8,19].

Some studies show that women with PROM at term who are not in labor, should have labor induced, usually with an oxytocin infusion, to reduce the risk of maternal and neonatal complications. As much as possible Caregivers should allow an adequate time for the latent phase of labor and minimize digital vaginal examinations until the active phase of labor to decrease the rate of infection.

2.1. Clinical course after Premature Rupture of the Membranes

2.1.1 Maternal Risks

One of the hallmarks of PROM is a short latency between membrane rupture and delivery, which typically increases as gestational age at membrane rupture decreases. At term, half of expectantly managed gravidas give birth within 5 hours, and 95% do so within 28 hours [28]. Of all women with PROM before 34 weeks, 93% do so in less than a week [29]. After excluding those who need to give birth shortly after admission, 50–60% of those conservatively managed and treated with antibiotics for pregnancy prolongation will give birth within 1 week of membrane rupture [29]. Only approximately ≤5% of PROM mothers can expect fluid leakage to stop, and 86% of those with leakage following amniocentesis will reseal [20,21,22].

After PPROM, chorioamnionitis is the most prevalent and feared maternal consequence. This risk rises as the latency period lengthens and falls as the gestational age at PROM increases.[23]. Even though they are rare, major side effects of PROM that are conservatively treated close to the limit of viability include maternal sepsis (0.8%), maternal mortality (0.14%), and retained placenta and hemorrhage, which necessitate dilatation and curettage (12%).[24, 25].

2.1.2 Fetal and Neonatal Risks

PROM will complicate fetuses with, infection and fetal distress due to umbilical cord compression or placental abruption. Umbilical cord compression due to oligohydramnios is not uncommon after PROM. Frank or occult umbilical cord prolapse can also occur, particularly with fetal mal-presentation. Due to this, women with PROM have a higher risk for cesarean delivery for non-reassuring fetal heart rate (FHR) patterns than those with isolated preterm labor (7.9% vs. 1.5%). When PROM managed conservatively, it may be complicated with fetal death (1% to 2%) [26,27,28].

A multicenter randomized controlled trial called the PPROMT trial demonstrated that newborn sepsis While the immediate delivery group saw higher rates of respiratory distress and any mechanical support, infant morbidity and mortality increased in the expectant management group. Antepartum or intrapartum bleeding, intrapartum fever, postpartum antibiotic use, and lengthier hospital stays were also more common in the expectant management group [19].

3.OBJECTIVES

3.1 General objective

To investigate the perinatal outcome (PNO) including maternal outcome of term PROM (TPROM) among women who delivered in three teaching hospitals of Addis Ababa University (TAH, ZMH, and GMH).

3.2 Specific Objective

1. To determine sociodemographic factors associated with PNO of term PROM
2. To determine reproductive characteristics associated with PNO of term PROM
3. To determine obstetric factors with PNO of term PROM
4. Describe the maternal outcome of term PROM

4.METHODS AND MATERIALS

4.1 Study Design and Area

A. hospital based cross-sectional study with prospective data collection from 1 December to 31 May 2020 was conducted in three government teaching hospitals in Addis Ababa:Tikur Anbessa Hospital, Zewuditu Memorial Hospital, Gandhi Memorial Hospital. The three hospitals serve as referral hospitals for more than 36 health centers (and private institutions) in Addis Ababa (and for surrounding regional states). It was expected that all patients with PROM would be referred to hospitals as soon as diagnosed from health centers.

4.2 Study Population, Sampling and Inclusion/ Exclusion Criteria

The population of interest comprises pregnant women with term PROM. The study population incorporated all the pregnant women with term PROM who delivered at the selected three government teaching hospitals during the study period.

The study was done at three government teaching hospitals in Addis Ababa: Tikur Anbessa Hospital, Zewditu Memorial Hospital, and Gandhi Memorial Hospital. Women who delivered with the diagnosis of term PROM and their neonates during the study period were selected.

4.2.1 Inclusion criteria:

Pregnant women and their neonates who are delivered with term PROM at the three government teaching hospitals during the study period are included in the study by convenience sampling method.

4.2.2 Exclusion criteria are:

- Multiple pregnancy
- Study participants who delivered at other institutions and transferred/ referred after delivery to the three teaching hospitals
- Study participants who was referred or transferred to other hospitals because of different reasons
- Non-consenting women
- Critically sick women having difficulty to give consent

4.3 Sample size

Sample size was calculated using Epi info7 software Stat Cal by considering the following assumptions

Confidence interval of 95%;

Power of 80%;

Incidence of neonatal sepsis among neonates delivered with in <12 hours of rupture of membrane 9.3% and incidence of neonatal sepsis among neonates delivered after rupture of membrane of ≥ 12 hours being 21.2 % (Hailemariam Segni.et.al,2017)

So the sample size calculated is 276. By adding 10% lost follow up rate, the total sample size will be 304.

4.3.1 Sampling Technique

Those pregnant women complicated by term PROM and delivered at the three teaching hospitals (TAH, GMH, ZMH) during the study period who fulfilled the inclusion criteria were enrolled in the study until the calculated sample size would be completed.

4.4 Data Collection Methods

Data was collected from participants' clinical (maternal & neonatal) records and by interviewing participating women using a data collection format/ questionnaire (annex 1-4).

4.4.1 Data Collection Instruments

Data on socio-economic and demographic variables of mothers was collected by interviewing using structured pretested questionnaires. Data collection tools were prepared in English. The outcome of measure of this study was the maternal and perinatal outcome of term PROM.

4.4.1.1 Data Collection Procedures

Daily, all parturient delivered at each hospital were screened by the data collector assigned at each hospital whether they have term PROM by reviewing delivery clinical records and asking the parturient.

When a potential participant (one with term PROM) was identified by the data collectors, the data collectors were informing the potential participant about the study (information sheet & consent form annexed 1 and 2 respectively) and would ask for willingness to participate. Further data collection was initiated after ascertaining her consent. Recruitment, ascertaining consent & data collection was undertaking before discharge at a time participant were comfortable.

The data collector then entered data to the questionnaire from the clinical record and completes it by interviewing the participants. All participants (and their neonates) were followed till discharge.

At discharge, participants were informed about the need for follow up till 30 days of delivery to ascertain her (mother/ participant) and her neonate's condition. This follow up was expected to be at her follow up postnatal clinic and by mobile phone. She was informed that the data collector/ researcher would call her on the 14^{th} and 30^{th} day of delivery. After ascertaining consent for the follow up and phone call, she was requested to provide her mobile number and second and third possible alternatives in case her mobile fails to respond. These alternatives could be providing her husband's or any one whom she lives with Phone number, The name of her nearby health center to communicate with them about her medical chart at post-natal clinic or her neonatal medical chart at pediatrics OPD to review it was also asked by the data collectors to communicate after the discharge with phone call.

Data was collected by 6 midwives and 6 Gynecology and Obstetrics residents,3 neonatal ICU nurses and who were trained by principal investigators for one day and all conducted interview questionnaires. The training was given by English& Amharic and was about interviewing technique and filling questionnaires, selection of mothers and neonates. Data was collected from mothers who delivered after a diagnosis of term PROM who was found at Emergency Gynecology Outpatient Department, labor wards, post-natal wards, maternity wards, neonates with mothers of term PROM who were on their mother side or at NICU.

4.5 Study Variables

4.5.1 Dependent variables:

Intra Amniotic Infections
PPH
Postpartum pelvic infection
Surgical site infection
Wound dehiscence

Duration of hospital stay
Maternal death
Cord prolapses
Abruptio placenta
Apgar score
NICU admission
MAS
PNA
Respiratory distress
CS delivery
Instrumental Vaginal delivery
IUFD
Early Onset neonatal sepsis. END

4.5.2 Independent variables:

Age
Address
ANC follow up
Gravidity
Parity
Gestational age
Income
Educational status
Previous history of PROM
Medical comorbidity

4.6 Operational Definitions

a. *Clinical chorioamnionitis* (Intra Amniotic Infection): when a mother has two of the following features Maternal Temperature ≥ 38°c
b. Uterine tenderness
c. Foul smelling amniotic fluid through the vagina
d. Maternal or fetal tachycardia
e. Increased WBC count ≥ 15000 cells/mm

- ✓ *END_* a neonatal death that will occur in the first 7 completed days of neonatal age
- ✓ *Neonatal sepsis*: the presence of clinical signs of neonatal infection including respiratory distress, apnea, lethargy, abnormal level of consciousness, circulatory compromise (including hypotension, poor perfusion, need for inotropic support or volume expansion), poor feeding and/or temperature instability and or identification a pathogen on blood culture as or diagnosed and treated by their treating physician in the neonatal ICU before discharge.
- ✓ *Maternal Outcome*: maternal outcome of the study participant whether favorable(good) or unfavorable (poor) outcomes.
- ✓ *Neonatal death*: death of a neonate within 28 days of delivery
- ✓ *PNO*: - Perinatal Outcome is, fetal or neonatal outcome of the study participant whether favorable(good) or unfavorable (poor) outcomes.

- ✓ *Poor(bad) Perinatal outcome*: adverse fetal and neonatal outcome like IUFD, END or Neonatal death,5th minute Apgar of less than 7, Neonatal admission, Neonatal sepsis, Respiratory distress, Neonatal jaundice, Perinatal asphyxia etc.)
- ✓ *Poor (bad) maternal outcome*: includes adverse maternal complications like maternal infection, maternal fever, post-partum hemorrhage
- ✓ *PROM*: Pregnant mothers who were diagnosed to have prelabour/premature rupture of membrane that is rupture of membrane before the start of labor diagnosed by one, some or all of the following methods: History, speculum examination, pad test, or amniotic fluid volume by ultrasound. When there as difficulty in diagnosing PROM, the most senior treating physician (residents and consultant) diagnosis was taken
- ✓ *Term PROM*; - Prelabour rupture of membrane at or after 37 completed weeks of GA by the most reliable milestone. How GA is ascertained?
- ✓ *Postpartum PID*: Pelvic infection diagnosed by treating physician up to 30 days of delivery (postpartum period).

- ✓ When there was dilemma or difference on clinical diagnosis, for both on maternal on obstetrics and neonatal side between different physicians, the diagnosis made by the most senior physician (resident or consultant) were selected and taken.

First data was checked for completeness and consistency before enter to the computer. Then it was coded and entered to SPSS statistical software version 25 for analysis. Descriptive statistics like frequency, measure of central tendency was used to describe study participants. Association of independent variable with the maternal and perinatal outcome was done using logistic regression, a significant association of variables with outcome was determined using adjusted odds ratio (AOR) together with 95 % confidence interval. Variables with P-value ≤ 0.05 was declared as statistically significant.

Data quality was assured through careful design of structured questionnaire and data collection procedure. For the clarification of data collection instruments and familiarization of data collectors with instruments as well as to estimate the time required for one study participant, pretest was done on 15 samples, 5 in each of the three hospital of the study area. One day training was given for data collectors regarding data collection method, ethical issue and purpose of the study and the training was given by principal investigator (PI). Overall supervision was done by principal investigator and data double entry was used in SPSS data to check discrepancies.

4.7 Ethical Considerations

Before the beginning of the data collection, this study was reviewed and approved by Addis Ababa University College of Medicine and Health science Department Research Ethics Committee, ethically was secure and Official letters was provided to the hospital administrative of the three hospitals (TASH,ZMH,GMH) . An informed, voluntary, written and signed consent was taken from each study participant after explaining the purpose, benefits, duration and any possible risk

of the study. Confidentiality of the study participants' information was ensured. Women who need termination of pregnancy or need medication at time of interview was provided after informing and discussing with the treating physician& documented order sheet. Verbal consent was taken from the treating physicin to collect data from the mother and the medical record. Consent was also taken from the mother for phone call after discharge.

4.8 Dissemination of the Result

The result of this study will be presented for Addis Ababa University School of Medicine and Health science, department of Gynecology and Obstetrics, three government teaching hospitals (TASH, ZMH,GMH) and for other concerned bodies working on maternal quality care in the study area. All possible effort will be made to publish the findings on peer reviewed journal.

5. RESULT

5.1 Sociodemographic characteristics of the study participants of term PROM pregnancy

In this study 300 participants among the 304-sample size were involved yielding a response rate of 98.7%. The prevalence of term PROM among the the total deliveries at the three hospital during the study period was 2.4% .Majority (67.3%, n=202) of the study participants were in the age group of 20-29 years with mean and SD of 27.2±4.6 respectively. One hundred thirty-one (41.6%) of the study participants had completed primary education and 72% (n=216) were housewife. Almost all (98.3%, n=295) were married and 60% (n=180) were orthodox in religion and three-fourth of the study participants had house hold monthly income of 3201-5250 Ethiopian Birr.

Majority (79.1%) of the poor composite perinatal outcome were in the age group of 20-29 years and also it accounts 16.8% (34/202) its age category observant. Poor composite perinatal outcome was more prevalent (40.8%, n=11) in mothers who have no formal education. And private employers (24.8%), n=8) and married (20%) had poor composite perinatal outcome.

Table 1. the sociodemographic characteristics of participant who had a diagnosis of term PROM in three teaching hospital of Addis Ababa University

Variable	Composite Perinatal outcome		Total (%)	p-value	OR with 95%CI
	Poor(n=43)	Good			
Age					
≤19	1(5.6)	17(94.4)	18(6.0)	1	
20-29	34(16.8)	168(83.2)	202(67.3)	0.238	3.4(0.44, 26.73)
30-34	7(11.5)	54(88.5)	61(20.3)	0.474	2.2(0.25, 19.21)
≥35	1(5.3)	18(94.7)	19(6.4)	0.969	0.94(0.06, 16.33)

Education level					
no formal education	11(40.8)	16(59.2	27(9.0)	0.001	**10.1(2.49, 40.85)**
Primary	24(18.3)	107(81.7	131(43.6)	0.062	3.3(0.94, 11.49)
Secondary	5(5.3)	90(94.7)	95(31.7)	0.786	0.82(0.19, 3.57)
higher education	3(6.4)	44(93.6)	47(15.7)	1	
Marital status					
Single	1(20)	4(80)	5(1.7)	0.717	1.5(0.16, 13.81)
Married	42(14.2)	253(85.8)	295(98.3)	1	
Monthly income					
<3200	7(13.2)	46(86.8)	53(17.7)	1	
3201-5250	35(15.6)	189(84.4)	224(74.7)	0.659	1.2(0.51, 2.91)
5251-7800	1(5.3)	18(94.7)	19(6.3)	0.362	0.37(0.04, 3.18)
7801-10900	0	4(100)	4(1.3)	--	
Gravidity					
primigravida	25(16)	131(84)	156(52.0)	0.018	**1.7(1.64, 4.26)**
Multigravida	12(14)	74(86)	86(28.7)	0.522	1.4(0.49, 3.98)
Grand multigravida	6(10.3)	52(89.7)	58(19.3)	1	
Parity					
Nulliparous	25(6)	131(94)	156(52.0)	1	
Primiparous	6(26.1)	17(73.9)	23(7.7)	0.239	1.8(0.66, 5.15)
Multiparous	4(6.6)	57(93.4)	61(20.3)	0.075	0.37(0.12, 1.11)
grand multiparous	8(13.3)	52(86.7)	60(20.0)	0.623	0.81(0.34, 1.90)
History of Abortion					
Yes	9(15.8)	48(84.2)	57(19.0)	1	
No	34(14)	209(86)	243(81.0)	0.728	0.87(0.39, 1.93)
History of molar or ectopic					
Yes	1(33.3)	2(66.7)	3(1.0)	0.369	3.1(0.27, 34.23)
No	42(14.4)	255(85.6)	297(99.0)	1	
Number of antenatal cares					
1-3	14(18.4)	62(81.6)	76(25.3)	0.242	1.5(0.76, 3.05)
≥4	29(13)	195(87)	224(74.7)	1	
Place of ANC					
Health center	25(13)	168(87)	193(64.3)	0.361	0.74(0.38, 1.42)
Hospital	18(16.8)	89(83.2)	107(35.7)	1	

5.2 Obstetric characteristics of the study participants

More than half 52% (n=156) of the study participant were primigravida and 19%(n=57) had history of abortion. One percent of the study participants had a history of molar/ ectopic pregnancy and 3/4th (74.7%, n=224) of the participants had four and above antenatal care visit and majority (64.3%, n=193) were received antenatal care in the health center. The percentage of poor composite perinatal outcome were calculated in respect to each variable and the higher number of poor composite perinatal outcome were in the primigravida (16%, n=25) and those of having history of abortion (15.8%, n=9/57) and having less than 4 antenatal visit (18.4%, n=14) and those of having antenatal visit in the health center (13%, n=25) mothers.

Table 2. The obstetrics and labor characteristics of study participants

Variable	Composite perinatal outcome		Total (%)	p-value	OR with 95%CI
	Poor	Good			
Incompetent cervix					
Yes	0	1(100)	1(0.3)		
No	43	256(85.6)	299(99.7)		
Chorioamnionitis					
Yes	1(14.3)	6(85.7)	7(2.3)	0.997	0.99(0.12, 8.48)
No	42(14.3)	251(85.7)	293(97.7)	1	
GUSH of fluid in PROM					
Yes	43(14.4)	256(85.6)	299(99.7)		
No	0	1(100)	1(0.3)		
Wetness					
Yes	15(13)	100(87)	115(38.3)	1	
No	28(15.1)	157(84.9)	185(61.7)	0.615	1.2(0.61, 2.34)
has urgency					
Yes	1(33.3)	2(66.7)	3(1.0)	0.369	3.1(0.27, 34.23)
No	42(14.1)	255(85.9)	297(99.0)	1	
fluid linkage through cervix					
Yes	23(11.8)	97(88.2)	110(36.7)	0.936	1.1(0.53, 2.01)
No	20(10.5)	170(89.5)	190(63.3)	1	
fluid linkage through cervix with Valsalva					
Yes	9(16.1)	47(83.9)	56(18.7)	0.097	1.9(0.89, 3.93)
No	24(9.8)	220(90.2)	244(81.3)	1	
cord prolapse					
Yes	1(16.7)	5(83.3)	6(2.0)	0.213	0.99(0.03, 3.21)
No	32(10.9)	262(89.1)	294(98.0)	1	
Meconium					
Yes	3(8.6)	32(91.4)	35(11.7)	0.308	0.53(0.15, 1.81)
No	40(15.1)	225(84.9)	265(88.3)	1	
pad test for PROM diagnosis					
Yes	9(11.5)	69(88.5)	78(26.0)	1	
No	34(15.3)	188(84.7)	222(74.0)	0.142	1.4(0.63, 3.04)
antibiotic for given					
Yes	41(14.9)	234(85.1)	275(91.7)		
No	2(8)	23(92)	25(8.3)	1	
onset of labour					
Planned cs	1(100)	0	1(0.3)		
Spontaneous	29(13.2)	191(86.8)	220(73.3)	0.142	0.77(0.38, 1.57)
Induced	13(16.5)	66(83.5)	79(26.3)	1	
Augmentation started(n=221)					
Yes	7(10)	63(90)	70(31.7)	0.354	2.1(0.46, 8.87)
No	23(15.3)	128(84.7)	151(68.3)	1	

Vaginal delivery achieved					
Yes	33(13.7)	207(86.3)	240(80.0)	1	
No	10(16.7)	50(83.3)	60(20.0)	0.065	1.2(0.58, 2.72)
Duration of LFSOL (n=240)					
<8	16(16.5)	81(83.5)	97(40.4)	0.311	1.5(0.70, 3.06)
≥8	17(11.9)	126(88.1)	143(59.6)	1	
Duration of AFSOL (n=240)					
<6	20(17)	98(83)	118(49.2)	0.160	1.7(0.81, 3.62)
>=6	13(10.7)	109(89.3)	122(50.8)	1	
Duration SSOL (n=240)					
<1hr	16(15.1)	90(84.9)	106(44.2)	1	
1-2hr	16(15.5)	87(84.5)	103(42.9)	0.930	1.0(0.49, 2.19)
2-3hrs	1(3.8)	25(96.2)	26(10.8)	0.158	0.22(0.03, 1.78)
>3hrs	0	5(100)	5(2.1)	-	
Duration of third stage					
<15	24(14.2)	145(85.8)	169(70.4)	1	
16-30	9(12.8)	61(87.1)	70(29.2)	0.784	0.89(0.39, 2.03)
>30	0	1(100)	1(0.4)		

5.3 Labour characteristics of term PROM

For most (73.3%, n=220) of the term PROM mothers, labour established spontaneously and 26.3%(n=79) started labour by induction. All of them were primed with prostaglandin(misoprostol) due to unfavorable and intermediate bishop score. All of them were induced with an indication of PROM. From those of mothers who started labour spontaneously, 31.7% (n=70) were augmented. Sixty-five of them were in latent phase during augmentation and five were in active phase of labour. All the augmentation were done by oxytocin. Vaginal delivery was achieved in 80% of the study participants (80%, n=240). Almost sixty percent (n=59.6%) had ≥8hours a duration of LFSOL and 50.8% (n=122) had an AFSOL of ≥6hours.

Forty-four percent (n=106) of the study participants delivered within one hours of second stage of labor. Among the participants who delivered by caesarean section, all of the cesarean delivery was done by resident and sixty percent (n=36) of the incised skin were prepared by alcohol iodine and

40% (n=24) were by Savlon iodine. Almost all (96.7%, n=58) of the procedure were completed within one hr. and 95% (n=57) had no intraoperative complication. But there is one atony and one extensive adhesion. There is one planned CS and having poor composite perinatal outcome (low Apgar which had also IUGR) and 16.5% (n=13) of the poor perinatal outcome were from the induction of labour.

5.4 Indication of caesarean section

The most common indication (63.3%, n=38) for CS delivery of term PROM were NRFHRP (Non-reassuring fetal heart rate pattern) followed by grade 3 meconium stained amniotic fluid GII-IIIMSAF(n=12), previous CS scar (n=8), CPD(n=1) and malpresentation(n=1).

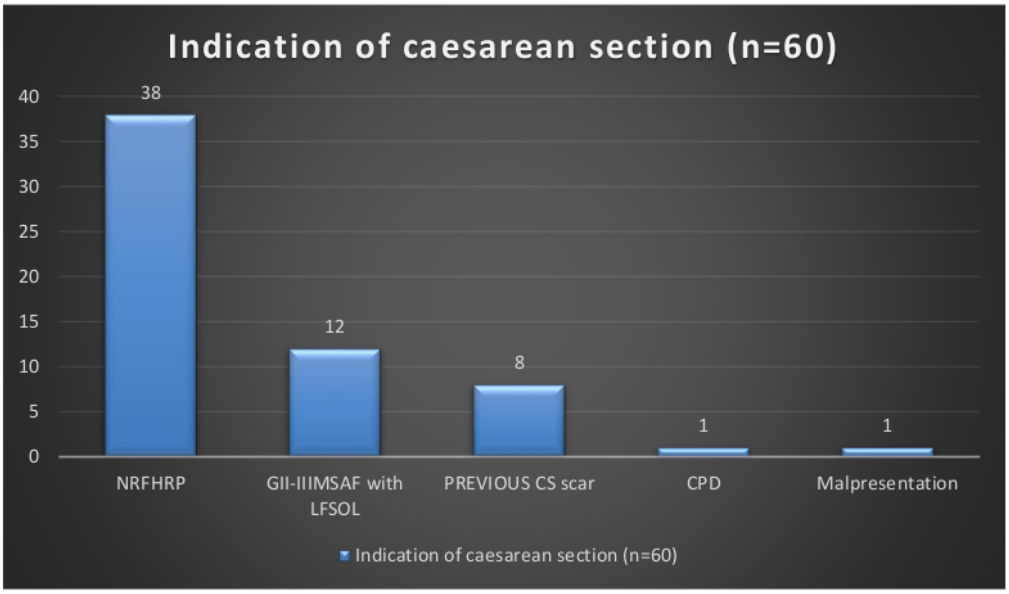


Figure 1.. Indication of caesarean section

5.5 Characteristics of the PROM in term pregnancy

In this study 3.3%(n=10) of the study participants had HIV/AIDS and HTN disorder of pregnancy and 2(0.7%) had antepartum hemorrhage. Only one participant had incompetent cervix and 2.3% (n=7) had chorioamnionitis. Almost all (99.7%, n=299) had gush of fluid in PROM and 1% (n=3) had urgency of fluid. Two percent (n=6) of the study participants had cord prolapse and 11.7 (n=35) had meconium sustained in the amniotic fluid. Almost all (91.7%, n=275) were given antibiotic and all of them given in intrapartum for the purpose of prophylaxes. There is no difference in poor perinatal outcome between chorioamnionitis and non-chorioamnionitis with in

the domain. All the poor perinatal outcome were present in the participants having gush of fluid in PROM and it accounts 14.3 form the total observant (n=43). prophylaxis antibiotic was given for 41 out of 43 cases and 2 out of 43 were not given.

The relation between mode of delivery and onset of labour:

The finding of the study indicates that onset of labour had a significant relation with mode of delivery. Study participant having spontaneous labour had 3.9 times increase rate of caesarean section compared to the participants for whom labour was induced (OR=3.9, 95%CI=1.59,9.38).

Table 3. The relation between mode of delivery and onset of labour

Variable	Caesarean section		p-value	OR with 95%CI
	Yes	No		
No labour	1	0		
Spontaneous	53	167	0.003	**3.9(1.59, 9.38)**
Induced	6	73	1	

5.6 Characteristics maternal complication of term prom pregnancy

The overall incidence of poor composite maternal outcome until the thirty day after delivery was 11% (n=33), but 89% (n=267) had good maternal outcome.81.8%(n=27) of the poor maternal composite outcome occurred within two weeks (fourteen days) after delivery.

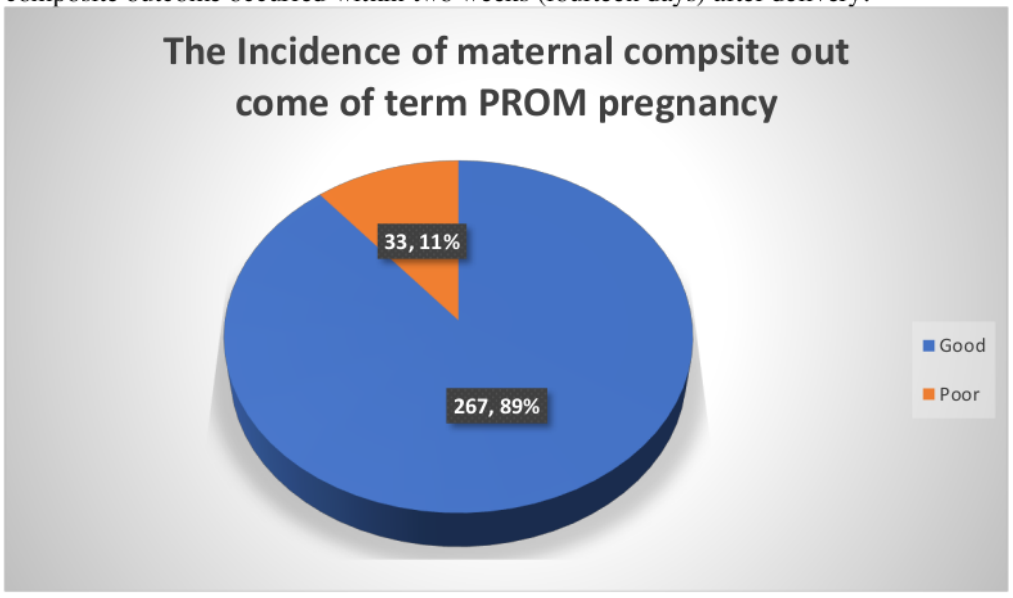


Figure 2.The incidence of composite maternal outcome in term PROM pregnancy.

At fourteen day of follow up, Ninety percent(n=271) of the study participants had no any compliant during post-partum follow up but 2.7% (n=8) had puerperal fever, 1.7% (n=5) had vaginal bleeding, 1.3% (n=4) had abnormal vaginal discharge and 4% (n=12) had wound site discharge. Nine percent (n=27) were developing complication and from those complication infection accounts 85.2% (n=23) followed by PPH (14.8%, n=4). 2% (n=6) developed SSI and 0% (n=3) treated with antibiotic. Until thirty day of maternal follow up, the overall prevalence of maternal infection, which was the commonest maternal complication, was 8%.

Table 4. The characteristics of maternal outcome in term PROM pregnancy.

Variable	Frequency	Percent
Complain during clinical follow up		
Routine PNC visit	271	90.3
Puerperal fever	8	2.7
Vaginal bleeding	5	1.7
Wound site discharge	12	4.0
Abnormal Vaginal discharge	4	1.3
Maternal complication		
Yes	27	9.0
No	273	91.0
Type of maternal complication (n=27)		
Infection	23	85.2
PPH	4	14.8
SSI in postpartum visit		
YES	6	2.0
NO	294	98.0
Cause (dx) of infection		
Postpartum upper genital infection	1	16.7
Postpartum fever	5	83.3
Types of treatment for infection		
Antibiotic	3	60
Wound care	2	40

5.7 Perinatal outcome characteristics of term PROM pregnancy

In this study, 14% (n=43) had poor composite perinatal outcome, while 86% (n=257) had good perinatal outcome.

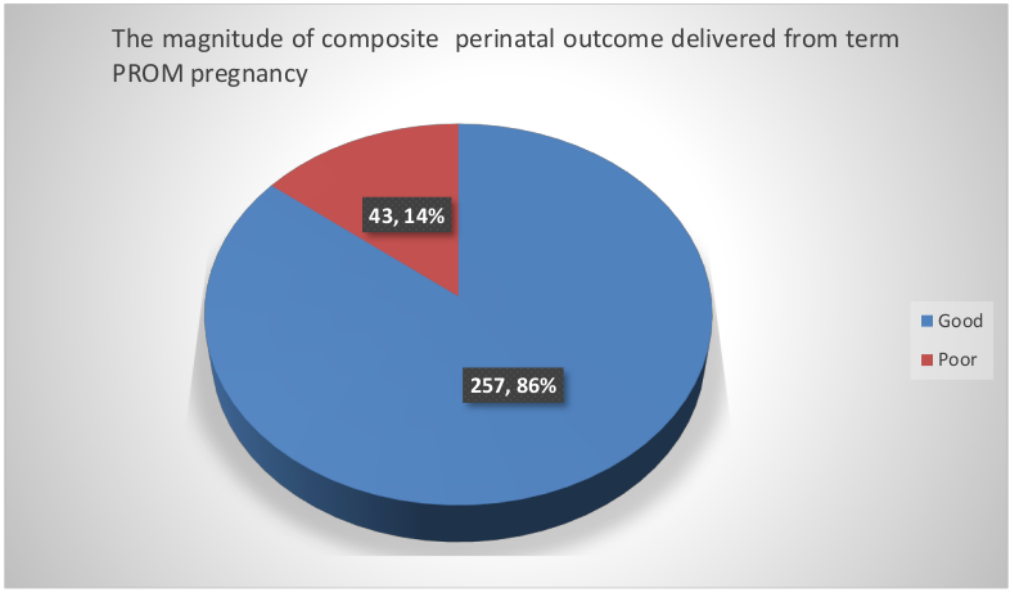


Figure 3. The magnitude of composite perinatal outcome among term PROM pregnancy.

About three forth of the mothers ,73.3%(n=220) delivered by SVD (spontaneous vaginal delivery). Eighty seven percent (n=261) of the participants had clear liqueur at time of delivery and 88.7% (n=266) had normal amniotic fluid volume at time of diagnosis of PROM, and 52%(n=156) new borns were male. Eighty-nine percent of the neonate had normal birth weight and 94.6%(n=281) had an APGAR score of ≥7 and above at five minutes of life, but there was 1% (n=3) IUFD and 1% (n= 3) ENND. More than eight percent (8.3%, n=25) had newborn complication that require admission to NICU. And among these, RD accounts thirty-six percent (n=9) followed by EONS (24%, n=8), Jaundice (24%, n=6) and PNA (8%, n=2).

Table 5. The characteristics of perinatal outcome in term PROM pregnancy

Variable	frequency	Percent
Mode of delivery		
SVD	220	73.3
VBD	3	1.0
Instrumental	17	5.7
CS	60	20.0
Amniotic fluid at delivery		

Clear	261	87.0
GI	19	6.3
G2	3	1.0
G3	17	5.7
Amniotic fluid volume at diagnosis		
Normal	266	88.7
Oligo	16	5.3
UK	18	6.0
Neonatal sex		
Male	156	52.0
Female	144	48.0
Birth weight of the neonate		
≤1900	10	3.3
2000-2499	13	4.3
2500-3999	267	89.0
≥4000	10	3.3
First minute APGAR		
IUFD	3	1.0
1-6	39	13.0
≥7	258	86.0
Five-minute APGAR		
ENND	3	1.0
1-6	13	4.4
≥7	281	94.6
Cause of ENND (n=3)		
Cardiac	1	33.3
RD	1	33.3
EONS	1	33.3
Gross congenital anomaly		
Yes	3	1.0
No	297	99.0
New born complication		
Yes	25	8.3
No	275	91.7
List of complication (n=25)		
EONS	8	32
Jaundice	6	24
PNA	2	8
RD	9	36

5.8 The determinant factor affecting the composite perinatal outcome

Educational level , gravidity and mode of cesarean delivery had an association with poor composite perinatal outcome by bivariate logistic regression. The multivariate logistic regression revealed

that study participant who had no formal education had 9.8 folds increased risk of poor composite perinatal outcome compared to mothers who had higher educational level (AOR=9.8, 95%CI=2.31, 41.9) and being primigravida had 2.4 folds increased risk of developing poor composite perinatal outcome compared to grand multiparous (AOR=2.4, 95%CI=1.86, 6.76). Study participants who hadn't achieved vaginal delivery had 1.8 folds high poor perinatal outcome compared to the participants who achieved vaginal delivery (AOR=1.8, 95%CI=1.49, 2.87).

Table 6. The association between independent and composite perinatal outcome by bivariate and multivariate logistic regression.

Variable	Composite perinatal outcome		p-value	COR	P-value	AOR
	Poor	Good				
Education Level						
No formal education	**11**	**16**	**0.001**	**10.1(2.49, 40.85)**	**0.002**	**9.8(2.31, 41.9)**
Primary	24	107	0.062	3.3(0.94, 11.49)	0.111	2.9(0.78, 10.52)
Secondary	53)	90	0.786	0.82(0.19, 3.57)	0.624	0.69(0.15, 3.07)
higher education	3	44	1		1	
Gravidity						
Primigravida	**25**	**131**	**0.018**	**1.7(1.64, 4.26)**	**0.043**	**2.4(1.86, 6.76)**
Multigravida	12	74	0.522	1.4(0.49, 3.98)	0.271	1.9(0.61, 5.84)
Grand multigravida	6	52	1		1	
Vaginal Delivery Achieved						
Yes	33	207	1		1	
No	**10**	**50**	**0.065**	**1.2(0.58, 2.72)**	**0.043**	**1.8(1.49, 2.87)**

6. DISCUSSION

This study investigated maternal, fetal and neonatal outcomes of term PROM and associated factors. PROM contributes to significant maternal and neonatal morbidity. Almost all obstetrician will face this challenge during his routine activities (2).

In this study 300 pregnant women had pre-labor rupture of membrane at term. The overall prevalence of term PROM among all deliveries after gestational age of viability at the three hospital during the study period was 2.4% .But this might not reflect the actual prevalence since it was the time when COVID -19 was global pandemic so that everyone was encourage to stay home

unless any option. And the exclusion criteria might also affect the magnitude. From those,300, only one participant had incompetent cervix and 2.3% (n=7) developed chorioamnionitis as a complication. This finding was lower than many studies done previously like the study done by Hailemariam S at Jimma University, study done by Shalev E., et al and others on expectant management of prelabour rupture of term PROM (12%) (27,28). This difference may be due to deference in the prevention of infection, protocol difference, participants susceptibility difference for bacterial colonization or just due to lack of diagnosis of subclinical chorioamnionitis before the occurrence of clinical chorioamnionitis since subclinical, chorioamnionitis was not being diagnosed in our study. The other explanation could be due to poor follow up of mothers to detect the complication early due to inadequate health personnel to laboring mother ratio. In this study almost all (91.7%, n=275) of the participant were given antibiotic for prophylaxis and this also be the other reason for the decreased rate of chorioamnionitis in these study participants.

Two percent (n=6) of the study participants had cord prolapse and 11.7% (n=35) had meconium sustained in the amniotic fluid. This finding was supported by the study of Schutte MF., et al (9). This risk of cord prolapse could be due to the sudden gush of fluid and protrusion of the cord toward the cervix.

In this study, among the seven mothers with chorioamnionitis one mother (14.3%) had poor perinatal outcome. The finding was congruent with the study done by Moretti M and Sibai B (8). This may be due to the fact that chorioamnionitis were a significant risk for respiratory distress and neonatal sepsis and all neonate of maternal chorioamnionitis were admitted to NICU. Those neonates admitted in NICU were considered as part of poor perinatal composite outcome. And the neonatal admission rate was 8.3%. In this study prophylaxis antibiotic was given for 41 out of 43 (95,3%) cases of poor outcomes and 2 out of 43 were not given. This could be due to that most of the antibiotics given were for prophylaxis, not for therapeutic purpose. This could be due to that since many of them were delivered after prolonged duration after rupture of membrane or related to other confounding factors.

In our study from 300 deliveries of term PROM pregnancy, 14% (n=43) had poor composite perinatal outcome. This finding was higher than the study done by Moretti M and Sibai B (8). This difference may be due to difference in the management protocol of term PROM, labour follow up difference, alertness in obstetric care difference, or health provider proficiency difference or lack

of early diagnosis and treatment of chorioamnionitis due to differences in access to different laboratory investigation or delayed interventions.

There was 1% (n=3) IUFD and 1% (n= 3) ENND. More than eight percent (8.3%, n=25) had neonatal admission due to newborn complication and from those RD accounts thirty-six percent (n=9) followed by EONS (24%, n=8), Jaundice (24%, n=6) and PNA (8%, n=2). This finding was correlated with the study done by Mercer B, Arheart K (20)and it was higher. This may be due to different constraint for those for the occurrence of all the complications. The major one may be due to staff constraint then institutional set up regarding the investigation modalities and difference in the options of accessibility and use of available medical equipment or skill of birth attendants or practice of different management protocol for intervention.

Study participant who had no formal education had 9.8 folds increased risk of poor composite perinatal outcome compared to higher education (AOR=9.8, 95%CI=2.31, 41.9). This might be due to participants who had formal education might have better knowledge and awareness about the danger sign of passage of fluid per vagina as danger signs of pregnancy and may seek medical attention and management earlier than those who had no formal education who might have limited sources of information so that delayed interventions.

Primigravida had 2.4 folds increased risk of poor composite perinatal outcome compared to grand multiparous (AOR=2.4, 95%CI=1.86, 6.76). This may also be due to most of the time in multigravida duration of labour would be reduced while in primigravida labour may be delayed and associated risk of PROM might be prolonged as duration of labour extended which prolongs the the duration of exposure of the fetus for infection from the genital tract. The other reasons could be that primigravida ladies might have lesser experience of delivery and may consider passage of fluid per vagina as a normal finding so that they may not seek medical care early.

Study participants who didn't achieved vaginal delivery had 1.8 folds high poor perinatal outcome compared to achieved vaginal delivery (AOR=1.8, 95%CI=1.49, 2.87). Even though cesarean delivery is not directly associated with poor neonatal outcome, neonates who were delivered by CS might have other additional obstetrics indications like NRFHRP, CPD and MSAF which might increase the risk of poor perinatal outcome significantly so that poor perinatal out come may be associated with the other confounding obstetrics indication rather than directly to the mode of delivery.

Concerning to the maternal outcome, 2.7% (n=8) had puerperal fever, 1.7% (n=5) had vaginal bleeding, 1.3% (n=4) had abnormal vaginal bleeding and 4% (n=12) had wound site discharge. Nine percent (n=27) developed complication until 30 days of follow up. And from those maternal complications, infection accounts 85.2% (n=23) followed by PPH (14.8%, n=4), which is comparable with different previous studies and this is also expected complication of PROM since infection specifically genitourinary infections are the feared complications of PROM. More or less these findings were in line with the study done by Hillier SL, Martius J, Krohn M, et (23).

7. CONCLUSION

From 300 pregnant women who had pre-labor rupture of membrane,2.3% (n=7) developed chorioamnionitis.

Among 300 respondents with term PROM, significant number of newborns and mothers complicated with poor composite outcome which constituted 14% (n=43) and 11%(n=33) respectively. Maternal education, gravidity and mode of delivery had significant association with poor composite perinatal outcome for mothers complicated with term PROM. Study participant who had no formal education had 9.8 folds increased risk of poor composite perinatal outcome compared to higher education (AOR=9.8, 95%CI=2.31, 41.9).Primigravida mothers had 2.4 folds increased risk of poor composite perinatal outcome compared to grand multiparous (AOR=2.4, 95%CI=1.86, 6.76).Study participants who didn't achieved vaginal delivery had 1.8 folds high poor perinatal outcome compared to achieved vaginal delivery (AOR=1.8, 95%CI=1.49, 2.87).The overall prevalence of postpartum maternal infection was 8%

8. RECOMMENDATIONS:

We recommend that health care providers who follow and manage pregnant mothers with term PROM should give special attention specially for primigravida ladies and mothers with no formal education.

The government of Ethiopia should give emphasis to empower mothers with formal education.

We recommend researchers to do further research from the general population with strict criteria for diagnosis and management to determine the perinatal and maternal outcome.

Are we sure that most of our rural pregnant mothers consider premature rupture of membrane as danger sign of pregnancy???

9. STRENGTH AND LIMITATION OF THE STUDY

9.1 Strength

Incorporates both maternal and neonatal outcome.

Both mothers and neonates followed for complication for 1 month prospectively in addition to the cross-sectional study.

9.2 Limitation:

Lack of gold standard diagnostic test for some complications.

Since most of the postpartum follow up was by phone call, diagnosis of some postpartum complication would be less reliable.

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Annex 1: Information Sheet

My name is _____. I am working as data collector for the study being conducted in this hospital by Dr. Tazebachew Wudie Alemneh who is studying for specialty of Gynecology and Obstetrics at Addis Ababa University, College of Health, and medical Sciences. I kindly request you to give me your attention to explain you about the study and being selected as the study participant.

The study title: Perinatal and maternal outcome of term Prelabor Rupture of Membrane(PROM) delivered at three teaching hospitals in Addis Ababa(Tikur AnbessaHospital,Ghandi Memorial Hospital and Zewuditu Memorial Hospital) .

Purpose of the study: the finding of this study will have a paramount importance for women having term PROM to plan intervention program. More over the aim of this study is to write a research paper as a partial requirement for the fulfillment of a specialty program of Obstetrics and Gynecology for the principal investigator.

Risks and benefits: The risk of being participated in this is minimal. But it may take 20-30 minutes. There would not be any direct payment for participating in this study. If I get a need for interventions or need of referring your neonate to neonatal ICU,I will communicate with the treating physician and do.After you are discharged from this hospital, I will remind you if you miss your post-partum follow up and also will ask you about your condition.

Confidentiality; The data you will provide will be confidential. There will be no information that will identify you. The finding of this study will be general for the study population and will not reflect anything particular of individual person. No reference will be made in oral or written reports that could link participants to the research.
I will request you to give me your phone number (your relative or partner phone number) so that I will be able to call you after discharge.

Annex 2: Consent Form (English Version)

I have been informed that the objective of this study is the maternal and perinatal outcome of rupture of membrane at term. The result of this study is important to treat me and other similar mothers and used as a guide for the management of rupture of membrane at term. I had been also informed about the confidentiality of the questionnaires. The data collector requested me to participate in the study that would require my willingness to respond to an interview, to see my and my neonate medical charts and to call me with phone if needed. Therefore, with full understanding of the importance of the study, I agreed voluntarily to be part of the study.

AGREE_____
DISAGREE_____Date:_____

1. Participant's Phone Number:_____

2. First relative's Phone Number;_____

   Relation with the participant:_____

3. Second relative's Phone Number;_____

   Relation with the participant:_____

Annex 3: Consent Form (Amharic Version)

ቀን፡----------

<u>የስምምነት መግለጫ</u>

እኔ የዚህ ጥናት ዋና ዓላማ ቀኑ በደረሰ እርግዝና ጊዜ ምጥ ከመጀመሩ በፊት የሚፈስስ የሽርት ውሃ በእናትና በፅንስ ወይም በጨቅላ ህፃን ላይ ሊያስከትል የሚችለውን ተፅኖ ማጥናት መሆኑን ተረድቻለሁ። ስለጥናቱ ምስጢር ጠባቂነትም ተነግሮኛል። መረጃ ሰብሰቢው /ዋ/ም ጥያቄ እንደሚጠይቀኝ/እንደምትጠይቀኝ የኔንም ሆነ የልጄን የህክምና መዝገብ ሊያይ /ልታይ እንደሚችል/እንደምትችልና አንደአስፈላጊነቱ ስለመጠይቁ በስልክ ሊጠይቀኝ /ልትጠይቀኝ እንደሚችል /እንደምትችል ጠይቆኛል/ጠይቃኛለች። በመሆኑም ጥናቱ ለኔና ለሌሎች እናቶች ህክምናና ሌላም ጥቅም ሊኖረው እንደሚችል በመረዳት በጥናቱ ላይ ለመሳተፍ ፈቃደኛ መሆኔን እገልፃለሁ።

እስማማለሁ ----------

አልስማም----------

MRN_____

1. የኔ ስልክ ቁጥር----------

2. የሌላ 1ኛ ሰው (ዘመድ) ስልክ ቁጥር ----------

   የዝምድና ሁኔታ ----------

3. የሌላ 2ኛ ሰው (ዘመድ) ስልክ ቁጥር ----------

   የዝምድና ሁኔታ ----------

Annex 4: Questionnaires

A. Identification

AHNO	HOSPITAL NUMBER	Mobile NO 1_____	Mobile NO 2_____

B. Socio-demographic C. Reproductive characteristics D. ANC

BAGE	Age: ____ ____ years	BEDU	Education: Highest achieved: ____
BOCC	Profession/ occupation: - _____	BETH	Ethnicity
BMAR	Marital status	BREL	Religious affiliation
BINC	Monthly income family in Birr	BFAM	Family size (number of people living together)
CGR	Gravidity	CPAR	PARITY
CABR	Abortion	COTH	Molar/ ectopic
DANC	ANC: 1. Yes ___ 0. No ___	DNO	Number of ANC visits
DPLC	ANC place (multiple response): _____ _____ ___	DRSN	Reason for having no ANC: _____ _____ __

E. LABOUR

ELON	Onset of labor	0. Not in labour or induced (CS, laparotomy etc.) GOTO DELIVERY SECTION 1. Spontaneous onset GOTO E2 SECTION 2. Induced GPTO E1	3. Died before labour & delivery GOTO 4. Referred before labour & delivery GOTO 7. OTHERS (SPECIFY & COMPLETE ALL FORMS THAT APPLY) _____

E1. INDUCTION & RIPENING

	Indication for induction (± RIPENING) i.e., termination of pregnancy	1. Post-term pregnancy____ 2. PROM____ 3. Abruption placentae___	4.DM 5. Hypertensive disease 6.Others Specify)_____.	
HIB	BISHOP SCORE	_____/ 13		
HIRM	Cervical ripening method used	0. NO RIPENING 1. Misoprostol 2. Dinoprostone	3.Dinoprostone 4.Others(Specify)___	
HIIM	Induction method (Multiple response is possible)	1. Oxytocin 2. Misoprstone1 3. Others (specify) _____	Has the induction led to **initiation of contractions**	1. yes 0. No
	Duration of induction ± ripening initiated to failed induction diagnosed	___ hours _____minutes	Possible reason/s for failure of induction ± ripening	1. __ 2____ _
HID	Duration from initiation of Induction (± cervical ripening) to at least 1 contraction/10 min/ 4 hrs			___ hr___min

E2. AUGUMENTATION

	WAS LABOR AUGUMENTED	YES NO _____	IF NO, GOTO E3 LABOR DURATION	
	Cervical dilatation augmentation initiated at ?	_____ cm (0 if no dilatation though she was in labor)	Duration of labor at initiation of augmentation	___Hrs
	Duration of initiation of augmentation to delivery	____ hours ____Min	Method of augmentation (multiple response)	_____

	tetanic contraction (≥ 6 contractions / 10 min	1. Yes 0. No	Was adequate contraction achieved?	1. Yes 0. No
	WAS VAGINAL DELIVERY ACHIEVED	1. Yes	0. No (Reason)_____	

E3. Duration of labor

HIDL	Duration of the latent phase (≤***1 contraction till 5 CM***	_____ hours & _____MINUTES	Duration of the ***active phase (from 5 cm***	___ hrs & ___minutes 0 if no progress to active phase
HIDS	Duration of the second stage	___ minutes ____ hours [0 if not in 2nd stage	Duration of the third stage of labor	___ hrs ____min [0 if no progress to third stage
	Total number of vaginal examination during labor and delivery (+ CERVICAL RIPENING): _____		Total number of vaginal examination after rupture of membrane (including speculum examination for diagnosis): _____	

F. CESAREAN SECTION

	Planning of operation (PREGNANCY TERMINATION)	1. Planned/ elective ____ 2. Urgent (planned within < than 24 hours ⁄ not in labour) ____ 3. Emergency in labour ____ 4. Others (specify) ____	Primary surgeon	1. Consultant_____ 2. Resident (specify year) _____ 3. Others (specify) - _____
	Indication (Primary)	1. One previous CS _____ 2. Two previous CS 3. CPD (relative) 4. Mal- presentation/ position ____ 5. NRFHP _____ 6.Others(Specify)_____	Skin preparation (multiple response)	1. Savlone _____ 2. Iodine _____ 3. Alcohol _____ 9. Others (specify) __
	Vaginal preparation	0. None _____ 1. Savlone _____ 2.iodine_____ 3. Normal saline_____ 4.Others(specify)____	Abdominal wall incision	1. Lower transverse _____ 2. Pfanesteine _____ 3. Sub umbilical vertical _____ 4. Para median _____ 9.Others(Specify)_____ _____

	Duration of surgery	_____ hours _____ minutes	Total blood(Whole blood) transfusion	
	Other blood products given		Total blood loss	
	Type of cesarean section	1. Lower transverse _____ 2. Lower vertical (DeLee) _____ 3. Classical CS _____ 4. Inverted T _____ 9. Others (specify) _____	Indications for any other than lower transverse CS:	_____ _____ _____ _____ _____ _____
	Placenta delivery method (multiple response)	1. Cord traction _____ 2. Manual removal _____ 3.Not known	In case of placenta previa , more on delivery of NB____	
	Intraoperative complication	0. NO 1. Atony 2. Extension 3. Difficult foetal extraction	4. Extensive adhesion associated with excessive bleeding 5. Bladder injury 6. Others(specify	

	HOSPITAL STAY AT EOPD ____HOURS ___ DAYS	Reason for more than 4-6 hours stay at EOPD: 1.Lack of bed_____ 2.unsettled diagnosis	3. Others(Specify)____

H. ANTEPARTUM & INTRAPARTUM MATERNAL COMPLICATIONS

DHIV	HIV/AIDS	1. Yes __ 0. No ___ 9. Unknown__	Latest third TRIMESTER viral load	____
DDMP	Diabetes mellitus	1.Yes 0.No ___	Hypertension	1.Yes 0.No ___
DMD1	Any disease for which she is using STEROID (e.g., asthma)	1.Yes 0.No ___	Incompetent cervix	1.Yes 0.No ___
GCSA	Vaginal bleeding in 1st Trimester	1. Yes __ 0. No __	Vaginal bleeding in 2nd Trimester	1. Yes __ 0. No
GCSA	PROM	1. Yes ___ 0. No	APH	1. Yes 0. N o
GCHPT	Incompetent cervix	1. Yes ___ 0. No	Anemia	1. Yes ___ 0. No
GCHIV	Chorioamnionitis	1. Yes ___ 0. No	Congenital abnormality (Specify …)	1. Yes ___ 0. No
GCOLI	MORE IN LABOR COMPLICATIONS	1. Yes ___ 0. No ___		1. Yes ___ 0. No
GCCA M		1. Yes ___ 0. No		1. Yes ___ 0. No

PROM

	Symptoms		IF NO REPORT, ENTER 9	
	Gush of fluid	1. Yes ____ 0. No ____ 9. ___	Fowl smelling vaginal discharge	1. Yes ____ 0. No ____ 9. ___
	Wetness	1. Yes ____ 0. No ____ 9. ___	Urine leakage on cough etc. (stress incontinence)	1. Yes ____ 0. No ____ 9. ___
	Dysuria	1. Yes ____ 0. No ____ 9. ___	Amniocentesis before PROM	1. Yes ____ 0. No ____ 9. ___
	Urgency	1. Yes ____ 0. No ____ 9. ___	Others (specify)	1. Yes ____ 0. No ____ 9. ___
	Frequency	1. Yes ____ 0. No ____ 9. ___		

	SIGNS ON VAGINAL SPECULUM EXAMINATION CONFIRMING DX			IF NOT DONE OR NO REPORT, TICK 9
	Fluid leakage through the cervix without Valsalva	1. Yes ____ 0. No ____ 9. ___	Vernix	1. Yes ____ 0. No ____ 9. ___
	Fluid leakage through the cervix with Valsalva	1. Yes ____ 0. No ____ 9. ___	Cord prolapse	1. Yes ____ 0. No ____ 9. ___
	Meconium	1. Yes ____ 0. No ____ 9. ___	Others (specify)	1. Yes ____ 0. No ____ 9. ___
	Investigation CONFIRMING diagnosis of PROM			IF NOT DONE OR NO REPORT, TICK 9
	Nitrizine blue	1. Yes ____ 0. No ____ 9. ___	Dye test	1. Yes ____ 0. No ____ 9. ___
	Ferning test	1. Yes ____ 0. No ____ 9. ___	Others (specify)	1. Yes ____ 0. No ____ 9. ___
	Pad test	1. Yes ____ 0. No ____ 9. ___		
	TREATMENT			
	Antibiotic TREATMENT given	1. Yes ____ 0. No ____ 9. ___	GOTO ANTIBIOTIC	
	Steroid treatment given	1. Yes ____ 0. No ____ 9. ___	GOTO steroid	
	SURGICAL TREATMENT	1. Yes ____ 0. No ____ 9. ___	GOTO procedure?	

E4. DELIVERY: MULTIPLE FORMS TO BE COMPLETED FOR EACH MULTIPLE DELIVERY (IF NOT SINGLETON)

	Order of pregnancy	1. Singleton _____ 2. Multiple pregnancy A _____ 3. Multiple pregnancy B _____ 4. Multiple pregnancy C _____ 5. Multiple pregnancy D _____		6. Multiple pregnancy E _____ 7. Multiple pregnancy F _____ 8. Multiple pregnancy G _____ 9. Multiple pregnancy H _____	GOTO EACH DELIVERY FORM IF MULTIPLE
	Mode of delivery	1. Spontaneous vaginal delivery 2. Vaginal breech delivery 3. Vaginal instrument delivery		4.Cesarean section 5. laparotomy 6. Other (specify)	
	Amniotic fluid at delivery	0. Not applicable 1. Clear 2. G1	4. G3 5. Bloody 6. Not known		(0= UNKNOWN if died OR REFERRED before delivery without RM)
	Amniotic fluid volume	1. normal 2. Oligohydramnios		3. polyhydramnios 4. unknown	

G. NEONATAL OUTCOME

	Sex	1. Male ____ 2. Female ____ 3. Ambiguous ____		
	Birth weight	_____ grams		
	1ST MINUTE APGAR	_____		
	5TH MINUTE APGAR	_____		
	10TH MINUTE APGAR	_____		
	GROSS CONGENITAL ABNORMALITY	0.No 1.Yes (Specify)__		
	IF NEONATAL DEATH, NB AGE AT DEATH	1._____ HOURS _____ DAYS 2. NA	ENTER NA IF NOT NEONATAL DEATH	

	CAUSE OF DEATH	1._____ 2._____	ENTER NA IF NOT NEONATAL DEATH	
	CAUSE STILLBIRTH	1._____ 2._____ 3.NA_____	ENTER NA IF NOT STILLBIRTH	
	COMPLICATIONS IDENTIFIED DURING SPECIFC POSTPARTUM ASSESSMENT	Age of NB at detection_____		
#NCSEP	1.SEPSIS			
#NC1	2.Neonatal death			
#NC2	3.Apparently healthy			
	4. Others(Specify)_____			

ANTIBIOTIC USE

	Cycle: 1__ 2__ 3__ 4__ 5__ 6__ 7__ **Use separate form for each cycle**		What for?	1. Treatment 2. Prophylaxis 3. Unknown	4. 5. 9. Others (specify):
	INDICATIONS - specific (Multiple?)	**1. CS** **2. PROM** **3.Chorioamnionitis**	**2. postpartum PID** **3. SSI** **4. Infected episiotomy**		**5. Others (specify) -** **_____**
	Antibiotic given	**Timing** **1. Antepartum** **2. Intrapartum** **3. Postpartum**	**GA started____** **If postpartum, enter PP day**	**Dose/day**	**Duration**
	Ampicillin				
	Erythromycin				
	Ceftriaxone				
	Ceftriaxone				
	Metronidazole				
	Gentamycin				
	Others(Specify)__				

STEROID USE FOR LUNG MATURITY

	Cycle: 1 __ 2 __ 3 __ 4 ___ **Use separate form for each cycle**		GA initiated: __ _____ weeks	
	Steroid used	1. dexamethasone 2. bethamethasone 3. others(specify)___	Duration _____ days	Dose per day: _____ Total doses _____
	Any steroid related complication identified (specify):			

	Cycle: 1 __ 2 __ 3 __ 4 ___ **Use separate form for each cycle**		GA initiated: __ _____ weeks	
	Steroid used	1. dexamethasone 2. bethamethasone 3. others(specify)___	Duration _____ days	Dose per day: _____ Total doses _____
	Any steroid related complication identified (specify):			

I. MATERNAL POSTPARTUM CONDITION (within 30 days of delivery)

	Context/ Time of clinical review?	1. Before discharge ___ 2. At postnatal clinic ___ 3. At EOPD ___	4. After readmission to ward ___ 5. Phone communication ___ 6. Other (specify) ___	
	Reason FOR presentation (complaint) or phone call: (multiple response)	1. Routine postnatal/ discharge/ visit _____ 2. Puerperal fever _____ 3. Vaginal bleeding ____	4. Wound site discharge____ 5. Abnormal vaginal discharge - _____ 6. Others(Specify)_____ 9. NB related	
	Postpartum day assessment	**_____ day**		
	List postpartum maternal complications identified or persisting MULTIPLE RESPONSE	1. Infections 2. PPH	3. Anaemia 9. Others (specify)	
	Maternal condition at specific postpartum assessment /	1. Alive _____ 2. Dead _____	3. Unknown(specify why)____	
	If dead, CAUSE OF MATERNAL DEATH	1.PRIMARY CAUSE:_____ 2.Other COMPLICATION LEADING TO DEATH_____		Complete maternal death form
	MATERNAL HOSPITAL STAY AFTER ADMISSION (multiple response) TILL DISCHARGE OR DEATH	_____Days before delivery _____Days for delivery ± Induction ± ripening _____DAYS AFTER DELIVERY _____Days after readmission _____Others(Specify)	ENTER NA IF NOT APPLICABLE AS IN	

	Context/ Time of clinical review?	1. Before discharge ___ 2. At postnatal clinic ___ 3. At EOPD ___	4. After readmission to ward ___ 5. Phone communication ___ 6. Other (specify) ___	
	Reason FOR presentation (complaint) or phone call:	1. Routine postnatal/ discharge/ visit _____	4. Wound site discharge____	

	(multiple response)	2. Puerperal fever _____ 3. Vaginal bleeding ____	5. Abnormal vaginal discharge - _____ 6. Others(Specify)_____ 9. NB related	
	Postpartum day assessment	**_____ day**		
	List postpartum maternal complications identified or persisting MULTIPLE RESPONSE	1. Infections 2. PPH	3. Anaemia 9. Others (specify)	
	Maternal condition at specific postpartum assessment /	1. Alive _____ 2. Dead _____	3. Unknown(specify why)____	
	If dead, CAUSE OF MATERNAL DEATH	1.PRIMARY CAUSE:_____ 2.Other COMPLICATION LEADING TO DEATH_____		Complete maternal death form
	MATERNAL HOSPITAL STAY AFTER ADMISSION (multiple response) TILL DISCHARGE OR DEATH	_____Days before delivery _____Days for delivery ± Induction ± ripening _____DAYS AFTER DELIVERY _____Days after readmission _____Others(Specify)	ENTER NA IF NOT APPLICABLE AS IN	

POSTPARTUM COMPLICATIONS IDENTIFIED AT EACH VISIT/ DISCHARGE)

	List of Complications	Postpartum day detected	List of Complications	Postpartum day detected
	PID: Yes ___ No ___		PPH Yes ___ No ___	
	SSI: Yes ___ No ___		Others (specify	

POSTPARTUM INFECTION

	List clinical findings underlying the postpartum INFECTION(Multiple answer possible)	1. Fever 2. Tachycardia 3. Hypotension/ shock 4. Abdominal pain: 5. abdominal tenderness 6. Abdominal mass/mass 9. Fowl vaginal discharge 9.Others(Specify	# # # Location _____ Location _____ Location _____ Location _____ Size _____
	What was the cause / diagnosis of the infection (Multiple response)	1. Postpartum upper genital infection ___ 2. Postpartum lower genital infection/Episiotom ___	3. Others(Specify)_____
	Treatment provided (Multiple responses)	1. Antibiotics ___ 2. Laparotomy _____ 3. Incision for abscess drainage ___	4. Open surgical stitches _____ 5. Wound care 6. Others(Specify)_____

I2. SURGICAL SITE INFECTION (SSI)

	The incision complicated with SSI was after:	1. CS 2. laparotomy 3. Others (specify)	Postpartum days SSI diagnosed detected	_____ days postpartum
	list clinical findings of the abdominal wound	1. Erythema of wound: Yes __ No___ 2. Oedema/ swelling: Yes __ No___ 3.Exudate: Yes __ No___	7. Fascia wound dehiscence: Yes __ No___ 8. Evisceration: Yes __ No___ 9. incision opened by surgeon: Yes __ No___ 10. Organ/ space involvement: Yes __ No___ Specify:_____	

		4. Pussy/ fowl smelling discharge: Yes __ No__ 5. Skin wound dehiscence: Yes __ No___ 6.Subcutaneous wound dehiscence: Yes__ No_	10. Others Yes __ No___ Specify: _____	
	Other treatments provided			

PROM outcome

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