SOCIODEMOGRAPHIC AND CLINICAL FACTORS ASSOCIATED WITH PRETERM PREMATURE RUPTURE OF MEMBRANES AMONG PREGNANT WOMEN ADMITTED TO PUBLIC HOSPITALS OF WEST SHEWA ZONE, CENTRAL ETHIOPIA

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ABSTRACT

BACKGROUND: Preterm Premature Rupture of Membranes (PPROM) poses a critical public health challenge, especially in low- and middle-income countries where it leads to substantial maternal and perinatal morbidity and mortality. However, the specific factors influencing PPROM have not been well understood in Ethiopia. Therefore, this study sought to uncover factors associated with PPROM among pregnant women admitted to public Hospitals of West Shewa Zone, central Ethiopia.

METHODS: A hospital-based unmatched case-control study was conducted from January 1 to February 28, 2024, in four randomly selected public hospitals of West Shewa Zone. A total of 142 cases and 284 controls were recruited using systematic sampling. PPROM was confirmed by sterile speculum examination and clinical features. Data was collected through interviewer-administered questionnaires and analyzed using SPSS version 27. Bivariate and multivariable binary logistic regression analyses were performed to identify independent predictors, with statistical significance set at $p < 0.05$. Data was analyzed using SPSS software. Bivariate and multivariable logistic regression analyses were performed to assess the association between dependent and independent variables, with statistical significance set at a p-value < 0.05.

RESULTS: Pre-eclampsia during current pregnancy (AOR=6.41, 95% CI: 2.62-15.6), MUAC less than 23 cm (AOR=4.74, 95% CI: 2.08-10.7) and previous history of preterm PROM AOR=2.44, (95% CI: 1.21-4.91) were found to be significant determinants of preterm PROM.

CONCLUSION: This study identified pre eclampsia, maternal undernutrition, and previous history of preterm PROM as key determinants of preterm premature rupture of membranes. Strengthening antenatal care to enable early detection and management of hypertensive disorders, integrating maternal nutrition programs, and ensuring close follow up for women with prior PPROM are critical strategies to reduce recurrence and improve perinatal outcomes.

KEYWORDS: Preterm premature rupture of membrane, Central Ethiopia, Determinants, West Shewa Zone, premature rupture of membrane

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INTRODUCTION

Preterm premature rupture of membranes (PPROM) is defined as rupture of the amniotic sac before 37 completed weeks of gestation, resulting in painless leakage of amniotic fluid[1, 2]. Towards the end of pregnancy, the amniotic sac typically ruptures due to a combination of factors. These factors include programmed cell death, the activation of enzymes that degrade collagen, and physical pressure exerted by the fetus[3].

Globally, PPROM complicates about 3% of pregnancies[4]. Its impact weighs heaviest in low- and middle-income countries (LMICs), which bear most prematurity-associated neonatal deaths[5]. A cross-sectional Ugandan study, for instance, documented PPROM in 7.5% of pregnant women[6]. In Ethiopia, available studies reveal PPROM rates ranging from 1.34%[7] to 22.76%[8], with recent meta-analyses estimating a pooled prevalence of 6.58%[9].

Preterm PROM imposes substantial risks on both maternal and fetal health, accounting for one-third of preterm births (10). It drives approximately 15% of perinatal mortality and 33% of perinatal morbidity (11). Neonates face common complications such as respiratory distress syndrome, necrotizing enterocolitis, intraventricular hemorrhage, and hyperbilirubinemia[12,13], while mothers encounter heightened dangers including infection, disseminated intravascular coagulation, cervical incompetence, cord prolapse, placental abruption, and postpartum hemorrhage[13, 14].

The specific cause that leads to PPROM has not been documented. However previously conducted studies reported several factors associated with PPROM such as cigarette smoking, having history of previous preterm birth, urinary tract infection during recent pregnancy, being multiple pregnancy, having history abortion, gestational Diabetes mellitus, history of preterm PROM, abnormal vaginal discharge, vaginal bleeding, Middle upper arm circumstance (MUAC<23cm)[15-17].

PPROM happens in many premature births; is the cause for greater than quarter of preterm birth (PTB)[18, 19]; births before the full 37th week of gestation, and PTB is the leading cause of perinatal morbidity and mortality and the second leading cause under-five mortality, with numerous short- and long-term health threats affecting the world. Around 75% of the death could be prevented with early identification of risk factors and prompt intervention. In 2019, preterm births accounted for approximately 16% of deaths in this age group and 35% of neonatal deaths[20, 21]. Similar to other countries, complication from prematurity is the leading cause for neonatal mortality rate in Ethiopia. The three biggest causes of neonatal death are preterm delivery, complications of presumptive birth asphyxia, and infection in which majority of these problems are caused by PPROM[22].

Apart from mortality, complications arising from prematurity also contribute significantly to severe morbidity, necessitating prolonged hospital stays. These complications encompass respiratory issues, metabolic disturbances, neurological challenges, and infections such as intra-amniotic and postpartum infections[23-27].

The Ministry of Health has rolled out multiple initiatives, including scaling up advanced obstetric and neonatal services alongside tailored training manuals and guidelines, to enhance healthcare providers' competencies in managing and referring obstetric emergencies[28]. Despite substantial efforts by the Ethiopian government, maternal and neonatal mortality remain persistently high[29]. Therefore, in order to meet the Sustainable Development Goals, set by the United Nations for 2030, it is crucial to identify the risk factors that contribute to the occurrence of PPROM[30, 31].

Despite its impact on foetal and maternal health, the specific determinants of PPROM in Ethiopia have not been clearly elucidated, with previous studies often focusing broadly on premature rupture of membranes. Furthermore, the use of cross-sectional study designs in earlier research limited their ability to identify critical factors associated with PPROM. Therefore, this study aimed to identify Sociodemographic and Clinical factors associated with Preterm Premature Rupture of Membranes among Pregnant Women admitted

to Public Hospitals of West Shewa Zone of Central Ethiopia. The findings of this research are expected to inform policymakers, stakeholders, and relevant bodies in developing and implementing strategies aimed at improving maternal and neonatal health, thereby reducing adverse pregnancy outcomes.

Methods

Study design, area and period

An institution based unmatched case control study was conducted in West Shewa zone of Oromia regional state, central Ethiopia. West Shewa zone is one of the twenty-one[21] zones of Oromia and Ambo town is the zonal administrative of West Shewa which is located 114Km west of the capital Addis. According to the 2007 Census conducted by the Central Statistical Agency of Ethiopia (CSA), the total population of the zone is about2,058,676, of whom 1,028,501 are men and 1,030,175 are women. The Zone has eight[8] functional public hospitals and ninety-six health centers. The study was conducted from January 01, 2024 to February 30, 2024.

Population of the study

The source population for this study comprised all pregnant women with a gestational age between 280/7th to 366/7th completed weeks who were admitted to the maternity wards, including both labour and high-risk units, of public hospitals in the West Shewa Zone during the study period. Cases were defined as women admitted with a diagnosis of PPROM, including those with additional obstetric complications, while controls were women admitted with diagnoses other than PPROM. Gestational age was primarily determined based on a reliable last normal menstrual period (LNMP) or, when LNMP was uncertain, by an early ultrasound scan performed before 24 weeks of gestation. In the absence of both, gestational age was estimated using fundal height measurements and clinical records. The diagnosis of PPROM was confirmed clinically by a painless gush of fluid per vagina, sterile speculum examination showing pooling of amniotic fluid in the posterior fornix, and supportive findings such as changes in uterine size or amniotic fluid volume.

Sample size determination

EPI info software version 7.1.1 was used to calculate the sample size using the double population proportion formula to estimate the sample size required for an unmatched case-control study. The following assumptions were considered to estimate the required sample size for the study: a 95% confidence level, 80% power, Vaginal bleeding as a risk factor with a lowest odds ratio of 2.58 (16), the proportion of controls with exposure 79.3%, and the proportion of cases with exposure 90.8%. Case to control ratio of 1:2 was employed. The final estimated sample size with assuming of 10% non-response rate was 426 with 142 cases and 284 controls.

Sampling techniques and procedure

Among eight public hospitals in the zone, four hospitals were randomly selected namely; Ambo general hospital, Gedo general Hospital, Inchini general hospital and Ambo University referral hospital. Cases were recruited using a convenience sampling approach and controls were selected using systematic random sampling technique. Prior to study commencement, hospital records were reviewed across participating facilities to identify eligible cases and controls. The sample size was then allocated proportionally to each hospital according to the anticipated number of cases and controls, as illustrated in the diagram below (Figure 1).

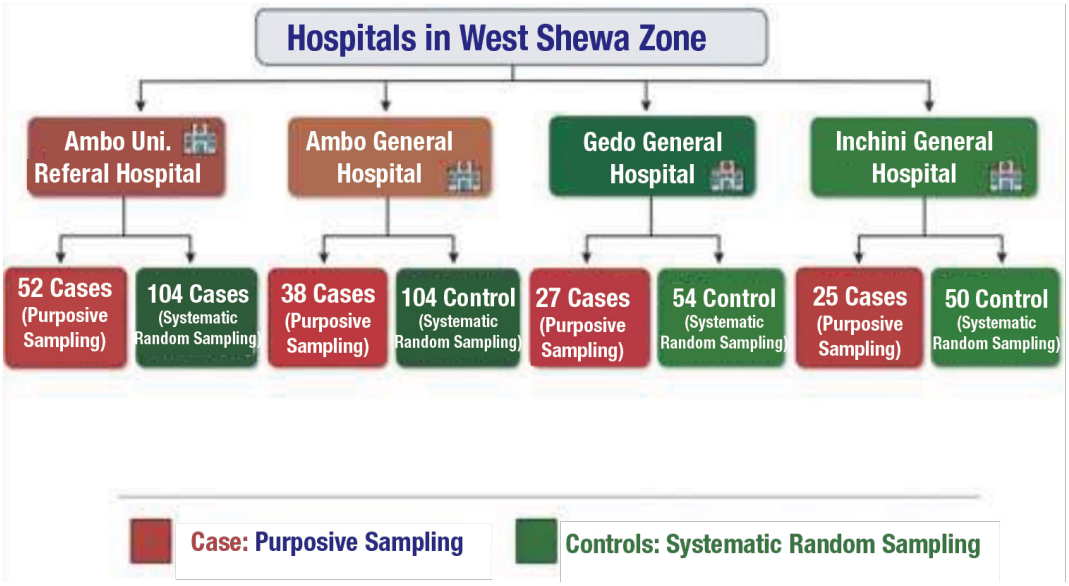

Figure 1: Schematic presentation of sampling procedure.

Variable of the study

Dependent variable: Preterm premature rupture of membrane

The independent variables in this study were grouped into four major categories. Socio-demographic factors comprised maternal age, marital status, residence, educational status, occupational status, and religion. Obstetric factors encompassed gestational age, antenatal care contacts, gravidity, parity, history of vaginal bleeding during pregnancy, prior PROM, previous preterm birth, abortion history, foetal presentation, and sexual intercourse during the third trimester of pregnancy. Medical factors consisted of pre-eclampsia, chronic cough, maternal anaemia, underweight, urinary tract infection, and gestational diabetes mellitus (GDM). Behavioural and reproductive health factors covered abnormal vaginal discharge, lower genital tract infections, smoking, khat chewing, and sleep habits.

Measurements

Preterm premature rupture of membrane (PROM), the dependent variable, was confirmed by clinical features (painless gush of fluid that leaks out of the vagina and a change in color or a decrease in the size of the uterus) and sterile speculum examination. Cases are mothers who were admitted to maternity wards of the selected hospitals and confirmed to have preterm premature rupture of membrane before the initiation of labor. Similarly, controls were mothers who were admitted to maternity wards of the selected hospitals with the diagnosis other than preterm premature rupture of membrane[32].

Gestational age was measured from reliable last normal menstrual period or early ultrasound scan before 24 weeks gestation to estimate gestational age[33].

Mid upper arm circumference was measured halfway between the tip of the shoulder (olecranon process) and the tip of the elbow (acromion process) to the nearest 0.1 cm. An insertion type MUAC tape that is non-elastic and non-stretchable was used to take the measurement. The measurement was taken at the mid-point on the relaxed non-dominant arm, without any clothing and with optimal tape tension (not too loose or not too tight) following the standard instructions and steps. An average of the two measurements was used for analysis. Women with average MUAC measurements of less than 23 cm were classified as having "undernutrition" while those with MUAC ≥ 23 cm as "no undernutrition[34].

Data collection tool and procedure

A questionnaire was adapted from a different literature [16, 17, 32, 35] and was designed to obtain participant information on socio-demographic characteristics, obstetric and gynaecologic characteristics, medical and behavioural characteristics. The questionnaire was initially developed in English and the translated into the local languages (Afaan Oromo) before being translated back to English. Statistically, Cronbach's alpha was performed, which is a measure used to assess the quality of our employed instruments. The result was 0.89, which was within acceptable ranges. Data were collected by interviewer-administered questionnaires by eight midwives and supervised by two master's holders.

Data quality control

Two days training was given to all the data collectors and supervisors. A pre-test was carried out on 5% (22 women) in Ginchi Primary hospital, which is located in West Shewa Zone but was not included among the study hospitals. Based on the findings of the pre-test, some modifications were undertaken. Data was also collected in Afan Oromo, the local language to prevent misinterpretation and pretest was conducted. To minimize recall bias, we limited questions to pregnancy related events that mothers could reasonably remember, and whenever possible, responses were cross checked against clinical records. Interviewer bias was reduced through standardized training of data collectors, use of a structured and pre tested questionnaire translated into the local language, and close supervision during data collection. Finally, double data entry was performed to check the consistency of the data.

Data processing and analysis

The collected data were coded, cleaned and entered into Epi data version 3.1 and exported to SPSS version 27 for analysis. Descriptive statistics such as mean, median, frequency, and percentage were used. Bivariate logistic regression analysis was used to identify candidate variables for multivariable logistic regression. Variables with p-value less than 0.25 were entered to multivariable logistic regression analysis to identify an independent determinant factor among explanatory variables. Adjusted odds ratio (AOR), 95% confidence interval (CI), and p-value less than or equal to 0.05 was used to decide a statistically significant association with the outcome variable. Hosmer- Lemeshow model test were done to check the model fitness before the final regression model and it was found to be 0. 692. Multicollinearity was checked by using variance inflation factor (VIF).

Results

Socio-demographic Characteristics of Study Participants

A total of 426 pregnant women (142 cases and 284 controls) participated in this study making a response rate of 100%. The age of respondents ranged from 18 to 37 years with the mean age of 24 ± 4 years for cases and 27 ± 5 years for controls. Majority of cases 138 (97.2%) and 278 (97.9%) of controls were married. One hundred forty (98.6%) of cases and 278 (97.9%) of controls were Oromo in Ethnicity. Regarding their educational status, 54 (38%) of cases and 95 (33.5%) of controls haven't attended formal education (Table 1).

Table 1: Socio-demographic characteristics of pregnant women admitted in public hospitals of the West Shewa zone, central Ethiopia, 2024 (N=426).

Variables	Categories	Cases (%)	Controls (%)
Age	18-24	79 (55.7)	154 (54.2)
	25-34	57 (40.1)	123 (43.3)
	≥ 35	6 (4.2)	7 (2.5)
Marital Status	Single	4 (2.8)	6 (2.1)
	Married	138 (97.2)	278 (97.9)
Place of residence	Urban	88 (62)	182 (64.1)
	Rural	54 (38)	102 (35.9)
Religion	Orthodox	67 (47.2)	137 (48.3)
	Muslim	26 (18.3)	60 (21.1)
	Protestant	44 (31)	77 (27.1)
	Others®	5 (3.5)	10 (3.5)
Educational status	No formal Education	54 (38)	95 (33.5)
	Primary (1-8)	35 (24.6)	60 (21.1)
	Secondary (9-12)	37 (26.1)	73 (25.7)
	Certificate and above	16 (11.3)	56 (19.7)
Mothers Occupation	Government Employee	29 (20.4)	66 (23.2)
	Private Business	32 (22.5)	65 (22.9)
	Housewife	76 (53.5)	143 (50.4)
	Daily Labourer	5 (3.5)	10 (3.5)

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Obstetrics Characteristics of the Respondents

There was no significant difference among cases and controls regarding ANC contacts. Almost all 130 (91.5%) of cases and 276 (97.2%) of controls had ANC contacts for their current pregnancy. Majority of cases 91 (64.1%) and 166 (58.5%) controls were attending their ANC at Hospitals. About two third of cases and controls had cephalic presentation. Eighty-one (57%) of cases and 143 (50.5%) of controls were primigravida. Among multigravida mothers nearly two thirds of case (62.1%) and 68.4% of controls had the preceding birth interval of 24 months. The proportion of mothers who had multiple pregnancy and polyhydramnios were low both among cases and controls (Table 2).

Table 2: Obstetrics characteristics of pregnant women admitted in public hospitals of the West Shewa zone, central Ethiopia, 2024.

Variables	Categories	Cases (%)	Controls (%)
Gravida	Primigravida	81 (57)	143 (50.5)
	Multigravida	61 (43)	141 (49.5)
Parity	Nulliparous	81 (57)	143 (50.5)
	Primiparous	32 (22.6)	76 (26.7)
	Multiparous	29 (20.4)	65 (22.8)
ANC contacts	No	12(8.5)	8(2.8)
	Yes	130(91.5)	276(97.2)
History of vaginal bleeding	No	102 (71.8)	264 (93)
	Yes	40 (28.2)	20 (7)
History of preterm birth	No	33 (54.1)	77 (54.6)
	Yes	28 (45.9)	64 (45.4)
History of PROM	No	34 (55.7)	76 (54.6)
	Yes	27 (44.3)	65 (46.1)
Foetal Presentation	Cephalic	90 (63.4)	181 (63.7)
	Breech	49 (34.5)	94 (33.1)
	Shoulder	3 (2.1)	9 (3.2)
Indication of admission	Pre-eclampsia	42 (29.6)	64 (22.5)
	Oligohydramnios	37 (26.1)	63 (22.2)
	APH	10 (7.0)	28 (9.9)
	Decreased foetal movement	10 (7.0)	16 (5.6)
	Others*	43 (30.3)	113 (39.8)
Abnormal Vaginal discharge	No	124 (87.3)	245 (86.3)
	Yes	18 (12.7)	39 (13.7)
Sexual intercourse after 7 months	No	120 (84.5)	220 (77.5)
	Yes	22 (15.5)	64 (22.5)

Footnote: *Severe anaemia, preterm labour, gestational DM and foetal growth restriction

Medical Characteristics of the Respondents

Concerning maternal medical problem about 12% of cases and 23% of controls have experienced different medical illnesses during this pregnancy. Among the mentioned medical illnesses, Pre-eclampsia accounts for 29.6% of cases and 22.2% of controls. History of chronic cough was reported among 21 (14.8%) of cases and 36 (12.7%) of controls.

Behavioural Characteristics of the Respondents

Regarding behavioural characteristics of respondents about 10% of cases and controls had sexually transmitted infection during their current pregnancy. None of the cases and controls had history of using cigarette, cocaine, and chat. About 3% of both cases and controls have history of lifting heavy weight since they become pregnant. Fall injury was reported among 13 (9.2%) of cases and 11 (3.9%) of controls. Regarding the sleep habit nearly half (46.9%) of the cases and about one third (32.4%) of the controls reported to sleep less than 8 hour per day. Genital tract infection was reported among 54 (38%) of cases and 37 (13%) of controls.

Determinants of Preterm PROM

The bivariate binary logistic regression revealed that variables like educational status, ANC contacts, place of residency, history of preterm labor, pre-eclampsia, history of vaginal bleeding, previous

history of PPROM, MUAC and genital tract infection have shown statistical association with PPROM

After controlling for the possible effects of confounders in multivariable binary logistic regression; MUAC <23 cm, Pre-eclampsia and previous history of preterm PROM have shown statistical association with PPROM.

As a result, pregnant women with a MUAC cm of less than 23 cm had five-fold increased odds of PPROM (AOR=4.74, 95% CI: 2.08-10.7). Similarly, among pregnant women diagnosed with Pre-eclampsia, the odds of PPROM were about six times greater (AOR=6.41, 95% CI: 2.62-15.6). Moreover, pregnant women with previous history of preterm PROM had 2.44fold increased odds of PPROM (AOR=2.44, 95% CI: 1.21-4.91) (Table 3).

Table 3: Bivariate and Multivariable logistic regression analysis for factors associated with PPROM among women admitted to public hospitals in West Shewa Zone, Central Ethiopia, 2024 (N=426)

Variables	Categories	PPROM		COR (95% CI)	AOR (95% CI)
		Cases (%)	Controls(%)		
Educational status	No formal Education	54 (38)	95 (33.5)	1.98 (1.04-3.80)	1.0 (0.41-2.43)
	Primary	35 (24.6)	60 (21.1)	2.04 (1.02-4.09)	1.11 (0.38-3.26)
	Secondary	37 (26.1)	73 (25.7)	1.77 (0.89-3.51)	0.66 (0.22-1.94)
	Certificate and above	16 (11.3)	56 (19.7)	1	1
ANC contacts	No	12(8.5)	8(2.8)	2.421(1.28-4.54)	1.41 (0.39-4.11)*
	Yes	130(91.5)	276(97.2)	1	1
Residence	Urban	98 (69)	244 (85.9)	1	1
	Rural	44 (31)	40 (14.1)	2.74 (1.68-4.46)	0.48 (0.09-2.40)
History of preterm labour	No	22 (22.7)	75 (77.3)	1	1
	Yes	39 (37.1)	66 (62.9)	2.01 (1.09-3.74)	
	0.86(0.21-3.65)				
MUAC	<23 cm	123 (86.6)	149 (52.5)	5.87 (3.43-10.1)	4.74 (2.08-10.7)
	≥23 cm	19 (13.4)	135 (47.5)	1	1
Pre-eclampsia	No	99 (69.7)	267 (94)	1	1
	Yes	43 (30.3)	17 (6)	6.82 (3.72-12.5)	6.41 (2.62-15.6)*
Vaginal Bleeding	No	102 (71.8)	264 (93)	1	1
	Yes	40 (28.2)	20 (7)	5.18 (2.89-9.27)	1.83 (0.31-10.8)
Previous history of PPROM	No	20 (22.2)	70 (77.8)	1	1
	Yes	41 (36.6)	71 (63.4)	2.02 (1.08-3.79)	2.44 (1.21-4.91)*
Genital tract infection	No	88 (62)	247 (87)	1	1
	Yes	54 (38)	37 (13)	4.09 (2.53-6.65)	1.54 (0.35-6.71)

1-Reference category, *: p-value less than 0.05

DISCUSSION

This unmatched case-control study aimed to investigate the factors influencing PPROM. The study findings indicated that having a MUAC of less than 23 cm, experiencing pre-eclampsia, and no ANC contacts were statistically associated with PPROM.

Pregnant women diagnosed with Pre-eclampsia, the odds of experiencing PPROM were nearly five times higher. This finding aligns with results from a study conducted in southern Ethiopia, indicating consistency in the relationship between hypertensive disorders and PPROM across different regions[35]. The increased risk of PPROM in women with hypertensive disorders during pregnancy may be attributed to several physiological mechanisms. Pre-eclampsia may lead to reduced blood flow to the uterus, which affects the normal invasion of cytotrophoblasts into spiral arterioles. This abnormal invasion, coupled with endothelial dysfunction, can result in placental ischemia and damage to placental endothelial cells. These conditions contribute to premature weakening of the fetal membranes and increase the likelihood of early rupture[36].

Pregnant women with a MUAC cm of less than 23 had four-fold increased odds of PPROM. This is in line with the results of the study conducted in Southern and North West Ethiopia[16, 35]. This is related with collagen formation being impaired by nutritional deficits, especially those involving micronutrients like vitamin C or ascorbic acid. The body is shielded by ascorbic acid against oxidative stress-related degenerative processes. Collagen must also be boosted and stabilized by serving as an enzymatic cofactor. Micronutrient deficiencies in the diet can cause capillary hemorrhage and weakened collagen, which can result in PPROM[37].

This study also revealed that a previous history of preterm PROM was significantly associated with recurrence of PPROM in the current pregnancy. This finding aligns with global evidence, which consistently demonstrates that women with prior PPROM are at increased risk of recurrence[38]. Similar study conducted in Ethiopia also highlighted recurrence as a well-established risk factor[9]. The possible justification for this recurrence lies in several mechanisms. Structural or biological predispositions such as cervical insufficiency, uterine anomalies, or persistent connective tissue weakness, may render the membranes more vulnerable to rupture[39, 40]. Additionally, subclinical intrauterine infections and chronic inflammatory processes can compromise membrane integrity across pregnancies[41]. Therefore, women with a history of PPROM should be considered a high-risk group in subsequent pregnancies, warranting closer surveillance, early interventions, and preventive strategies such as cervical length monitoring, infection screening, and timely referral to specialized care.

Conclusion

This study identified pre-eclampsia, maternal undernutrition, and previous history of preterm PROM as determinants of preterm premature rupture of membranes. These findings emphasize the need for integrated antenatal strategies—strengthening maternal nutrition, vigilant monitoring of hypertensive disorders, and targeted follow up for women with prior PPROM to mitigate recurrence and improve maternal and neonatal outcomes. Targeted interventions addressing these modifiable risk factors could substantially improve maternal and neonatal outcomes, particularly in resource-limited settings like Ethiopia.

Strengths and limitations of the study

The strength of this study lies in its ability to efficiently investigate numerous potential risk factors for PPROM in a resource-constrained environment where this significant pregnancy complication is prevalent. By comparing pregnant women diagnosed with PPROM to a control group unaffected by the condition, the study has identified critical sociodemographic and clinical factors contributing to PPROM within this specific population.

As a hospital-based case–control study, the risk of Berkson's bias cannot be entirely excluded, since both cases and controls were drawn from admitted patients. We attempted to mitigate this by restricting controls to admissions unrelated to PPROM and adjusting for confounders. Additionally, recall bias and the limited geographic scope may affect the generalizability of the findings.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with to the research, authorship, and/or publication of this article.

Author Contribution

Both authors conceived and designed the study, establishing the research framework and methodology. D.N.G collected data, and performed the analysis. G.G.B. provided critical insights during the data interpretation and supervised the overall project. Both authors contributed to drafting the manuscript, with D.N.G. leading the initial writing and G.G.B. providing revisions and critical feedback. Both authors reviewed and approved the final version of the manuscript.

Ethics statement

The study adhered to the Declaration of Helsinki. Ethical approval was obtained from the Ambo University Ethical Review Committee (Ref. No. PG 23/480/2024). Subsequently support was secured from the Arsi Zonal Health Department and the participating health facilities. After providing a comprehensive explanation of the study's objectives, potential risks, and benefits, written informed consent was obtained from all participants. Confidentiality and anonymity were assured, and participants had the right to withdraw at any time.

Data availability Statement

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

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