



Effect of Preterm Premature Rupture of Membranes on Neurodevelopmental Outcome of Infants Among Preterm Infants Born at Hawassa Comprehensive Specialised Hospital of Sidama Region, Ethiopia, 2022

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Objective

To verify whether preterm premature rupture of membranes has effect on neurodevelopmental outcome of Infant among preterm infants born at Hawassa Comprehensive Specialised Hospital of Sidama region, Ethiopia, 2022.

Methodology

Study area

Hawassa Comprehensive Specialised Hospital.

Study design

A prospective cohort study design will be conducted for 2 years and 6 months from March 1/2022 to August 30, 2024.

Source population

All preterm infants born at Hawassa Comprehensive Specialised Hospital of Sidama region.

Study population

All preterm infants born at Hawassa Comprehensive Specialised Hospital and admitted to the neonatal intensive care unit from March 1/2022 to August 30/2024 and meet inclusion criteria.

Eligibility criteria

Inclusion criteria

- Mother has no medical complications during pregnancy
- Fetus born alive
- Permanent resident in Sidama Rregion.

Exclusion criteria

- Severe malformation.

Sample size determination

Given the observational nature of the study, we did not calculate a sample size.

Sampling techniques

All preterm infants will be recruited consecutively from preterm infants admitted to neonatal intensive care unit from March 1/2022 to August 30/2024. The preterm infants will be categorized into Exposed group (preterm infants born after preterm PROM) and non-exposed group (preterm infants born after spontaneous preterm labour) and followed until 2 years of age to assess neurodevelopmental outcome of infants.

Study variables

- Dependent variable: Neurodevelopmental outcome of infants
- Independent variable
- Socio-demographic factors
- Birth weight
- Gestational Age
- Previous low birth weight
- Previous abortions.

Operational definitions

Preterm PROM was diagnosed when membrane rupture occurred in the absence of regular uterine contractions and the time from membrane rupture to delivery was greater than 12h.

Spontaneous preterm labour was defined as the presence of regular, painful contractions (more than four in 30 min) with intact membranes or, if membrane rupture had preceded the onset of regular uterine contractions, the time from rupture to delivery was 12h or less.

Data collection procedure

- Maternal sociodemographic. Clinical and obstetrics variables will be collected using a structured questionnaire. The diagnosis of PROM will be based on clinical assessment, and ultrasonography findings
- Neurodevelopmental examination of the infants will be done by a child neuro psychiatrist or neurologist not involved in the intensive care of the infants and unaware of maternal and neonatal history.
- Examinations will be done at discharge from hospital and at 3 month, 6 month, 12 month and 24 months of corrected age.
- Neurological evaluation of the newborns will be based on the methods of Amiel-Tison and Grenier [1].
- The Bayley scales of infant development will be used to assess cognitive development (Mental Developmental Index (MDI)) at 12 to 24 months.

Infants will be grouped into four categories of outcome according to their final examination:

- **Group one:** Unimpaired= normal neurological status and Bayley MDI > 84;
- **Group two:** Minor impairment= abnormalities of tone or reflexes but functionally normal or borderline (71-84) Bayley MDI;
- **Group three:** Moderate impairment= spastic diplegia or hemiplegia with a Bayley MDI \geq 71;
- **Group four:** Severe impairment= spastic tetraplegia and/or severe mental retardation (Bayley MDI < 71).

This classification is similar to that proposed by De Vries, *et al.* [2].

A total of 12 Midwives. 6 supervisors and 1 pediatric neurologist or psychiatrist will be involved in the data collection process.

Data quality control

Three day intensive training will be given on how to assess the cognitive development (Mental Developmental Index (MDI)) at 12 to 24 months and on interviewing techniques using standard checklist and structured questionnaire. Supervision will be conducted. Double data entry will be done and the questionnaire will be pretested on 5% of total sample size at Dila referral Hospital During data collection, continuous supervision will be done by the supervisors and principal investigator [3-5].

Data processing and analysis

- The data will be entered into Epidata software and exported to SPSS software for windows version 23. for analysis. Descriptive statistics will be computed.
- One-way Anova and post hoc comparisons with Scheffe's procedure will be used.
- X2 test or Fisher's exact test will be used to compare categorical variables.

Ethical Consideration

Prior to data collection appropriate ethical clearance and supportive letter will be obtained from the Ethical Review Committee of Hawassa College of Health Science. Written permission will be

obtained to undertake the study from Hawassa Referral Hospital. Participation in the study will be based on voluntary base and the participants will be informed about the right to withdraw at any time from the study. Confidentiality will be assured by using anonymity.

During the period of the study it will be the responsibility of Hawassa referral hospital to manage PROM before 33 weeks of gestation with antibiotic prophylaxis and screening for amniotic infection and fetal distress, as well as to manage preterm PROM at 33 to 34 weeks of gestation, with induction of labour or caesarean section 24 to 48h after rupture.

Written consent will be requested from every study participant included in the study during data collection time after explaining the objectives of the study. For this purpose, a one page consent letter was attached to the cover page of each questionnaire stating about the general objective of the study and issues of confidentiality which was discussed by the data collectors before proceeding with the interview.

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