Letter to Editor

Effect of preterm premature rupture of membranes on neurodevelopmental outcome of infants among preterm infants born at Hawassa comprehensive specialized Hospital of Sidama Region, Ethiopia, 2022

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Abstract

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

Methods and materials: A prospective cohort study design will be conducted for 2 years and 6 months from March 1/2022 to August 30/2024. A total of 12 Midwives, 6 supervisors and 1 pediatric neurologist or psychiatrist will be involved in the data collection process. All preterm infants will be recruited consecutively from preterm infants admitted to neonatal intensive care unit from March 1/2022 to August 30/2022. 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 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.

Objective

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

Methodology

Study area: Hawassa Comprehensive Specialized 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 30/2022 and meet inclusion criteria.

Eligibility criteria

Inclusion criteria:
Mother has no medical complications during pregnancy
Fetus born alive
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Permanent resident in Sidama Region

Exclusion criteria:
- Severe malformation
- Children with genetic disorders

Sample size determination

Given the observational nature of the study, no data from the previous study about the proportion of neurodevelopmental disability among preterm infants born from preterm premature rupture of membrane and to obtain sufficient exposed group the is preterm infants born from preterm premature rupture of membrane in a reasonable period of time, 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 30/2022. 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 12 h;

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 12 h or less [1].

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 neurological assessment [2].

The Bayley scales of infant development will be used to assess cognitive development (Mental Developmental Index (MDI)) [3].

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

- An overall level of impairment was defined based on the worst outcome from the 5 domains
- Instead of classifying impairments into ‘none’, ‘mild–moderate’ and ‘severe’ impairment, we classify as none, mild, Moderate–severe impairment

Participants who receive a positive response to the following questions into the ‘moderate-severe’ category: with spastic diplegia or hemiplegia or spastic tetraplegia according to neurological examination.

- D2 Is the child’s development between 6-12 months behind corrected age?
- RC1 Does this child have difficulty with understanding outside of familiar context?
- EC2 Does this child have difficulty with speech (<10 words/signs)?
- FM2 Does this child have difficulty with the use of both hands?
- GM2 Is this child’s gait non-fluent or abnormal reducing mobility
- GM4 Is this child unstable or needs to be supported when sitting?

Participants who received a positive response to any of the other questions are classified as having mild impairment with abnormalities of tone or reflexes according to neurological examination.

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 training will be given on how to assess the cognitive development (Mental Developmental...
Index (MDI) 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.

**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 as well as pre term infants. Preterm infants with neurodevelopment impairment will be linked to appropriate intervention service.

Written consent will be requested from mothers/care givers 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.

**Questionnaire on neurodevelopmental outcomes of pre term infants**

**References**

