Methodological considerations of neonatal *near miss* in Sergipe, Brazil

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***Abstract*—Introduction: The concept of *near miss* is being increasingly used as a tool to assess and improve the quality of care. Objective: This research aimed to discuss the methodology used to identify neonatal *near miss* in public and private services in the city of Aracaju in the state of Sergipe, Brazil. Method: The method used in the construction of the study "Neonatal *Near miss* in Sergipe, Brazil", was a case-control study, in which for each identified case, two controls were selected, was carried out in two public maternity hospitals and in a private maternity hospital in the capital of Sergipe, one of them being a high-risk maternity hospital in the period from 1 year from 2014 to 2015. Results: In the referred maternities in Aracaju, 16,245 births were evaluated. At the High Risk Maternity Hospital, 241 newborns were classified as neonatal *near miss*. At the usual Risk Maternity Hospital in the capital of the State of Sergipe, 50 newborns were classified as neonatal *near miss*. In the usual risk and high risk maternity hospital, 10 newborns were classified as neonatal *near miss*. Conclusion: The identification of neonatal *near miss* cases made it possible to analyze risk factors related to assistance to mothers and newborns.**

Keywords—Near miss; Early neonatal mortality; Risk factors.

I. INTRODUCTION

The neonatal period represents almost half of deaths in children under five years old. About 4 million newborns die during the first week of life worldwide [1]. Approximately 99% of these deaths occur in low and middle income countries, with high neonatal mortality rates generally associated with inadequate care during prenatal care and birth [2]. In Brazil, half of infant deaths occur in the early neonatal period [3].

It is necessary to investigate the causes of neonatal deaths so that programs with actions directed to the factors that influenced the occurrence of death can be implemented4. The most important factors related to neonatal mortality are: prematurity, intrapartum asphyxia, infections, congenital malformations and maternal factors [5].

The definition of *near miss* is being increasingly used as an instrument to assess and improve the quality of care, especially in the area of maternal health. In this sense, a standard definition and identification criteria were established, by the World Health Organization (WHO), to characterize the cases of maternal *near miss* (NMM). NMM is defined as "a woman who almost died, but survived a complication during pregnancy, during childbirth, or within 42 days after termination of pregnancy". The neonatal *near miss* (NNM), in turn, is determined as a newborn that has determinants of severity during the first days of life, almost died, but survived during the neonatal period [3].

There is no international consensus about the criteria for classifying the newborn as NNM. According to a study by Avenant (2009), the use of markers was suggested based on respiratory insufficiency or dysfunction, infections and central nervous system dysfunction or failure. Later, in a study carried out by the World Health Organization (WHO), "2005 WHO Global Survey on Maternal and Perinatal Health", a definition was developed based on the most common causes of death: asphyxia and prematurity. The criteria used for neonatal *near miss* were gestational age at birth less than 30 weeks, very low weight and Apgar score, at 5 minutes of life, less than 7. The neonatal *near miss* rate estimated by the WHO, in this study, was 21.4 cases per 1,000 live births [6] [3].

Pileggi-Castro et al (2014) used analysis from two WHO studies: "Global Survey on Maternal and Perinatal Health" (WHOGS) and "Multicountry Survey on Maternal and Newborn Health" (WHOMCS) and established neonatal *near miss* criteria, pragmatic criteria: birth weight <1750g, gestational age <33 weeks and Apgar at the 5th minute <7, and management criteria. Silva et al (2014) defined neonatal *near miss* as the newborn who had one of these criteria: birth weight <1,500g, Apgar score <7 at the 5th minute of life, mechanical ventilation, gestational age <32 weeks and congenital malformations. In 2015, the Latin American Center for Perinatology (CLAP) proposed the definition of neonatal *near miss* for newborns with pragmatic and / or management criteria [7][6][8][9].

It is necessary that the concept of *near miss* be an effective instrument for improving maternal and child health, so it is necessary to identify cases of *near miss* and analyze the respective indicators [10].

Although the neonatal *near miss* assessment identifies factors that cause the high number of deaths in the neonatal period, few studies have explored this important issue. It is necessary to expand efforts in an attempt to identify these factors that contribute to the high rate of neonatal deaths in developing countries.

Through this study, the authors propose to discuss the methodology used to identify neonatal *near miss* in public and private services in the city of Aracaju in the state of Sergipe, Brazil.

II. OBJECTIVE

This research aimed to discuss the methodology used to identify neonatal *near miss* in public and private services in the city of Aracaju in the state of Sergipe

III. METHOD

Study construction

A case-control study was carried out, through which for each identified case, two controls were selected. The study was carried out following the guidelines of the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) [11].

Study location:

The study was carried out in three maternity hospitals: a reference maternity hospital for pregnant women at high risk, a maternity hospital for pregnant women of habitual risk and a maternity hospital for pregnant women of habitual risk and of high risk.

Study duration:

The study was conducted during the period of 1 year from 2014 to 2015.

Target population:

The target population of the research was made up of newborns of pregnant women hospitalized for delivery, who met the inclusion and exclusion criteria previously defined.

Inclusion criteria:

Inclusion criteria were newborns of women who had their deliveries at the three maternity wards that were classified as a case or control.

Exclusion criteria:

Dead babies, malformed ones and newborns without information about vital status at birth or at discharge from hospital up to seven days were excluded.

Case Definition:

The classification criteria for neonatal *near miss* were the presence of at least one of the following criteria [3] [8]:

- Gestational age at birth <32 weeks;
- Very low birth weight (Weight <1500g);
- Apgar score at the 5 minutes of life <7.

Controls definition

The newborn was classified as a control if the following criteria were required:

- Being born immediately after the newborn case;
- Same sex as case;
- Idade gestacional maior ou igual a 37 semanas;
- Gestational age less than 42 weeks;
- Adequate weight for gestational age, according to weight x gestational age graph [12];
- Did not undergo procedures: venoclysis, phototherapy, hypoglycemia correction.

Data collection instruments:

The following instruments were used:

- Form consisting of 130 items, divided into:

Identification sheet - data related to the mother's identification and which were obtained after analyzing the medical record and interviewing the mother.

Medical records data - records obtained from medical records.

a. Data of mother's hospitalization b. Newborn data c. Childbirth data

Forms - obtained by interviewing the mother.

a. Mother's data b. Income data c. Data related to pregnancy d. Childbirth data

- Maternal and Child Research Record Books.

Gathering manual – explanatory document about each item of the form and that was used by the research members during data collection.

Variables analyzed

Data were obtained by analyzing medical records, checking the pregnant woman's card and in a manner referred to by the patient. The variables used were the following:

- Prenatal: if the mother went to any prenatal consultation.
- Smoking: whether or not she smoked during pregnancy.
- Alcohol: whether she drank or not during pregnancy.
- Illicit drugs: whether she used illicit drugs or not during pregnancy.
- Pre-pregnancy diseases: whether or not there was a disease during the previous pregnancy
- Complications in current pregnancy: if, during the current pregnancy, you had any condition such as, for example, premature amniorrhexis, hypertensive syndromes, preterm labor, urinary tract infection.

- Kristeller's maneuver: if pressure was applied to the back of the uterus during fetal expulsion by the on-call staff [13].
- Beginning of prenatal care: in number of weeks of gestation.
- Number of prenatal consultations: how many consultations were performed during prenatal care.
- Mother's age: calculated in years, based on the mother's date of birth.
- Number of pregnancies: quantified in numbers of pregnancies before the birth of the newborn.
- Number of live births: quantified in numbers of births.
- Number of years of schooling: how many years the mother studied.
- Area: classified as urban or rural.
- Marital status: if single, consensual, widowed or separated.
- Education: whether she attended school or not.
- Work: classified as home, employed with a formal contract, employed without a formal contract, autonomous, owner, unemployed, retired, student, civil servant.
- Type of delivery: normal, cesarean section or forceps.
- Broken bag: if it broke spontaneously or not, before delivery. It is the rupture of the water bag [14].
- Oxytocin: use or not during labor. It is a synthetic hormone used to induce or increase contractions of labor [14].
- Misoprostol: use or not during labor. It is a substance used to prepare the cervix [15].
- Abortions: quantified in numbers.
- Stillbirths: quantified in numbers.
- Anterior cesarean section: quantified in numbers.

Data collection technique

The research had the collaboration of three Federal University of Sergipe (UFS) postgraduate supervisors, three UFS master´s degree students and 20 undergraduate students in Medicine and Nursing, who took turns daily at the maternity hospitals in the capital of Sergipe, Aracaju, so that all births were checked and analyzed, with the aim of immediately identifying a newborn case and then the two newborn controls.

A form for the research was elaborated, after an extensive bibliographic review on the proposed theme and after several meetings, with questions that were considered relevant to the theme. The form contains 130 items referring to data related to medical records, patient identification, childbirth, mother, income and pregnancy.

Data collection was initiated and all live births at the maternity hospitals in the study were recorded in the respective books of the Maternal and Child Research, in order to have a reliable record of all births that occurred at the maternity hospital.

The team of researchers built a daily and uninterrupted scale, in which data collection was done twice a day, in the morning and afternoon shifts, every day of the week, including weekends and holidays. In each shift, there were at least two students in each maternity ward and a master's student supervising the collection. A data collection routine was established for all members of the research, so that everyone knew exactly how to proceed.

Initially, the researcher went to the maternity ward, at his pre-established time, with the lab coat and the identification badge. Those responsible for the sector were identified on the day, being requested the book of registration of live births and the book of orders and occurrences of maternity wards, in order to record in the book of research records all live births born from the last newborn (NB) that was registered in the previous shift. In the book, the following data were noted: mother's name, sex, date of birth, weight, first and fifth minute Apgar, gestational age by Capurro, whether or not it was classified as a neonatal *near miss* and whether or not it was classified as a control.

After noting in the research book the mothers 'names and the day and time of delivery, contained in the maternity record book, the newborns' medical records were checked in all wards of the ward and in the operating room, in order to identify the data concerning the neonatal *near miss* classification and their respective controls.

When the newborn was classified as a neonatal *near miss*, the survey form was filled out by analyzing the medical record and interviewing the mother of the newborn, after signing it in the Free and Informed Consent Form. In addition, in another section of the record book of the Maternal and Child Research, the following NB (newborn) data were also noted: date of birth, box number at the NICU (Neonatal Intensive Care Unit), mother's name, sex, date of discharge hospital and date of death, for greater control of neonatal *near miss* cases until the seventh day of hospitalization or until discharge.

The evolution of the neonatal *near miss* case was monitored for seven days in the Neonatal Intensive Care Unit (NICU) or in the Intermediate Care Unit (IMCU). The following data on the newborn were recorded in a section of the Maternal and Child Research record book: resuscitation, oxygen, mask, continuous positive airway pressure (CPAP), oxygen helmet or endotracheal tube, adrenaline, surfactant, umbilical vein catheterization, central venous access, venous dissection, peripherally inserted central catheters (PICC), antibiotic, blood transfusion and parenteral nutrition.

The two controls were also immediately identified, obeying the criteria already mentioned, and the form for 130 controls was also filled out for each control, through the analysis of the medical record and the

interview with the mother, after signing the informed consent form.

At the end of this process, in another section, at the end of the record book of the Maternal Child Survey, everything that had occurred during the collection shift, including the names of the cases and neonatal *near miss* controls that were collected and the pending issues for the other shift. This served to have greater control over what was done in each shift, in addition to functioning as a form of communication between the shifts. Communication was also made through e-mails, telephones and in person.

Ethical aspects

This research was planned in accordance with the declaration of Helsinki and resolution 466, of 2012, of the National Health Council. It was submitted to the UFS Research Ethics Committee, with CAAE: 274216214.8.0000.5546. Before the start of data collection, all patients signed the Free and Informed Consent Form (ICF).

Data analysis

The analysis performed was descriptive statistics, using absolute and relative frequencies, measures of central tendency and variability. As a measure of association, the odds ratio (OR) and its respective confidence intervals were calculated. Associations between groups were assessed using the Chi-Square test, in the case of categorical variables, and the Mann Whitney test, in the case of numerical variables. The level of significance (α) adopted was 0.05.

Then, a logistic regression analysis was performed, considering the variables, taking into account a p <0.20. The multivariate analysis was performed with the variables pre-selected in the previous step, according to the hierarchy presented in the conceptual model. The criterion established in this analysis step for the variables to remain in the model was p <0.05. The analysis was performed using the R program, version 3.3.1 (Core Team 2016) and the epiR package.

Pilot project

A pilot study was started at the High Risk Maternity on September 15, 2014, which lasted 30 days. During this period, the teams of master's students and students were trained in the field, in the morning and in the afternoon, during all days of the week. The Collection Manual and explanations in person to the team were used. Before the execution of the project, the entire team was registered in the Teaching and Research Centers of the Maternities and after registration of information from the researchers, they received badges necessary to enter the sectors of the maternity hospitals where the research would take place. The sectors used in the research were the Surgical Center, Wards, neonatal ICU (Intensive Care Unit) and medical records sector.

IV. RESULTS

During the period of one year, 16,245 births were evaluated in the referred maternity hospitals in Aracaju, Sergipe. At the High Risk Maternity Hospital, 5408 newborns were evaluated, 241 newborns being classified as neonatal *near miss* and 482 newborns as controls. There was a loss of 3.7% of the cases and 14.9% of controls, mostly due to failures in filling out the survey form. At the usual risk maternity hospital in the capital of the State of Sergipe, 10,002 newborns were evaluated and 50 newborns were classified as neonatal *near miss* and 100 newborns as controls. In the usual risk and high risk maternity hospital, 835 newborns were analyzed, with 10 newborns classified as neonatal *near miss* and 20 newborns as controls.

The analysis of maternal *near miss* cases allows the identification of a sufficient number of cases to study and understand the failures of the health system within a shorter period compared to studies on maternal death. This analysis would be more acceptable to those responsible for providing health services, since it is associated with a positive outcome. It is also possible to understand the perceptions of women in relation to the care received due to the interviews that the evaluation of cases *near miss* allows to carry out. Therefore, NNM case monitoring is increasingly used to check the quality of obstetric care [16]. Therefore, the adoption of criteria for the identification of neonatal *near miss* and strategies for its reduction would greatly improve the quality of maternal-fetal care.

In the selection of the criteria for the definition of neonatal *near miss*, this study used some characteristics determined by Pileggi et al. (2010) and Silva A. et al. (2014), in previous studies in which both studies used neonatal morbidity as an indicator , Apgar at the 5th min <7 and birth weight <1500g. However, in relation to gestational age, Silva A. et al. (2014) considered the gestational age <32 weeks and not less than 30 weeks, as defined by Pileggi et al. (2010). In this research, it was agreed with both studies cited in relation to the definition of the criteria of the Apgar and weight indicators, but the gestational age was defined according to that of Silva A. et al. (2014), for being more conservative, contributing to increase the sample volume of this research [3] [8].

As an alternative to minimize selection bias of the interviewed patients, the medical records and cards of the pregnant women were checked. Regarding the medical records, the verification of the records was done in duplicate, so that errors from the data not being identified by the researchers or by the employees' spelling were minimized.

The dimensioning of neonatal morbidity made it possible to identify a greater number of newborns at risk of dying, which may make it possible to carry out control measures. Preventing risk factors is one of the solutions to avoid unfavorable outcomes and, similar to maternal *near miss*, neonatal *near miss* can offer an ideal way to obtain important information about

prenatal care and assistance to the newborn. The identification of risk factors that contributed to a negative neonatal outcome can direct the use of resources to improve care for pregnant women and newborns..

V. CONCLUSION

The evaluation of *near miss* cases allows us to understand the failures of the health system and the care provided to mothers in the hospital environment, in addition to making it possible to carry out measures to control unfavorable outcomes through the prevention of risk factors both in prenatal care and in assistance to the newborn.

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