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Stress and its associated factors in mothers with preterm infants in a private tertiary care hospital of Karachi, Pakistan

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Study Protocol

Stress and its associated factors in mothers with preterm infants in a private tertiary care hospital of Karachi, Pakistan

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Abstract

Background

Preterm births are the leading cause of death worldwide. Preterm births not only have devastating effects on the newborn, but they also have psychological effects on the mothers. Identifying stress related to preterm births, and the factors associated with the stress among mothers with preterm infants is of great importance, for providing sound care to the newborns and their mothers. The aim of this protocol paper outlines an extensive approach to assess the level of stress and its associated factors among mothers with preterm infants.

Methods

An analytical cross sectional study design will be used to achieve the study objectives. A total of 235 mothers who had given birth to preterm infants will be recruited using consecutive sampling. Data will be collected using a self-developed questionnaire for socio-demographic characteristics, obstetric and gynecological characteristics, marital and familial characteristics, coping related factors and newborns characteristics of mothers with preterm infants. Perceived stress scale (PSS) will also use in the study to identify level of stress among mothers with preterm infants. Data will be analyzed through descriptive and inferential analysis in the Statistical Package for Social Sciences (SPSS) version 22.

Conclusion

This study will advance understanding of stress and the variables that influence it in mothers of premature babies. Health care providers would be able to take reference of the current study to conduct interventional studies for the mothers delivering the preterm infants.

Key Words: Preterm infants, perceived stress scale (PSS), perceived stress.

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Study Protocol

Background

Preterm births are rising at a larger rate globally. Each year about 15 million infants are delivered preterm around the world (1). Preterm births account for 28% of all the neonatal deaths worldwide (2). Pakistan is also striving hard to work on this challenging issue. Pakistan has 4th highest number of preterm births after India, China and Nigeria (1). In addition, preterm births are accountable for heavy burden of neonatal morbidity and mortality rates of the country. The prevalence of neonatal mortality in Pakistan is for every 1000 live births there are 42 neonatal deaths (2).

Preterm births create alarming effects on the newborn but at the same time, it creates distressing challenges for the mothers. In addition, these difficult challenges accounts for the advancement of stress in mothers. The outcome of early childbirth affects mother's decision and thinking capability, hence increases the pressure of having high risk newborn (3). The incidence of stress among mothers who had given birth to preterm infants are as elevated as 30-40% contrast to 6-12% in mothers with infants born at complete gestational period (5). This statistical value portrays a picture of the mental effects on the overall wellbeing of the preterm mothers.

One of the different ways to encounter this situation is working on the coping approaches of mothers with preterm infant. According to Karbandi et al., 2018, maternal coping is the attempt of the mother to eliminate or diminish stress and amplify tolerance. Furthermore, mothers of preterm infants use various coping strategies to minimize the stress in this demanding condition. Strategies used by the mothers for coping enclose a close connection with support system and emotional wellbeing of mothers with premature infants (3).

This literature is giving us an idea that there is a definite need to work on this area. This can be done by identifying the needs of the mothers and the newborn and incorporating effective coping strategies to reduce the stress associated with the preterm births.

Significance

Preterm births are escalating at a greater number building enormous burden of the morbidity and mortality globally. Thus, the mothers of the preterm have an increase need to reduce the stress level associated with the birth and care of preterm. In addition, there is a need for the diverse coping strategies for the mothers to cope with the demanding situation.

Nurses are an integral part in the collaborative care of the preterm and their mothers. This study will assist nurses identify the stressors of the mothers which will accompany following the birth of a preterm. Moreover, nurses would be able to facilitate mothers in recognizing the different coping strategies available for the mothers. Furthermore, nurses will be able to work jointly for the betterment in the care of preterm and also working for

the coping of the mothers in the challenging situation. This study is important at a bigger picture because it will identify stressors of the mothers and working on that stressors will help mother to care their preterm effectively. This will ultimately reduce the overall mortality and morbidity associated with the ineffective coping of the mothers following the birth of a preterm. As in whole, this research will facilitate to accomplish the sustainable development goal by reducing the mortalities and morbidities for both maternal and infants.

Research Questions

1. What is the level of stress among mothers with preterm infants in a tertiary care hospital in Karachi, Pakistan?

2. What are the factors associated with stress among mothers with preterm infants in a tertiary care hospital in Karachi Pakistan?

Methodology

Study Design

Quantitative research examines phenomena and situations that impact the population on a larger scale delivering factual data that can be conveyed via figures and numbers (6). The analytical cross-sectional study design will be incorporated into the study to identify stress and its associated factors among mothers with preterm infants. The analytical cross-sectional study design is beneficial when the plan of the study is to identify the prevalence of a problem, its associated factors, and the association between exposure and outcome (6). To ascertain an association between the level of stress, and its associated factors, an analytical cross-sectional study design was considered relevant for this study.

Study Population

The population of the study implies the group of all the subjects on whom the results of the study are based, and that can be generalized for the whole target population (7). The study population will be the mothers who delivered preterm infants in a private tertiary care hospital in Karachi, Pakistan. These preterm babies are treated in the NICU and then shifted to step-down units for teaching and training the mothers in handling the preterm infant. The mothers will be recruited from the NICU and the step-down units of a private tertiary care hospital in Karachi, Pakistan.

Study Setting

The surroundings, logistics, environment, and arrangements of the study setting are significant aspects that need consideration before commencing a research study (8). Data will be collected from a private tertiary care hospital in Karachi Pakistan. The inpatient service for preterm infants includes NICU, neonatal step-down units, and neonatal nurseries, catering to more than 50 patients per day. There will be a large pool of mothers from which the participants could be chosen. Moreover, people accessing the hospital come from different demographic regions, socio-cultural backgrounds, and educational statuses which may contribute to a

comprehensive picture of the study population.

Study Period

This quantitative analytical cross-sectional research study will be completed in a five-month period after approvals from the chief medical officer (CMO), and the ethical review committee (ERC).

Inclusion Criteria

- Mothers of age 18 years and above
- Gestational age of preterm below 37 weeks.
- Mothers who will be willing to participate and give consent.

Exclusion Criterion

- Mothers who could not communicate in the Urdu or the English language.

Sampling Method

A consecutive sampling method will be used for selecting participants. Consecutive sampling involves enlisting a group of people from the available population that meets the eligibility criteria over a particular period. Consecutive sampling is an enhanced approach as it minimizes bias in the study, as compared to the convenience sampling method (6).

Sample Size

The sample size will be calculated through open Epi software. The prevalence of stress among mothers with preterm infants is reported to be 75% (9). The reported prevalence of stress among mothers with preterm infants would be used to calculate the sample size for question no 1, with a 95% confidence interval, 10% room for error, and a non-response rate of 10% will also be adjusted. To achieve the study objective, the final sample size is determined as 73+7 i.e. 80.

The prevalence of co-morbidities among mothers with preterm infants is 38.41% and for mothers with term infants is 20.76% (10). Considering the proportions to calculate the sample size for question no 2, taking power of the study as 80, the confidence level of 95%, two-sided hypotheses, taking 1:1 ratio for unexposed and exposed for the sample, and the estimated prevalence ratio of 1.8; the approximate sample size came out to be 213. Adding the non-response rate of 10% i.e. 21 the final sample size is 234.

Since the sample size is higher for associated factors of stress among mothers with preterm infants (i.e., 234), the sample size of 234 will be required for the study.

Recruitment Process of Participants

The selection of relevant participants is fundamental for the correct interpretation of the population in a study (11). Firstly, permission for the research would be taken from the CMO of the hospital. Moreover, approval from the ERC of the Aga Khan University Hospital would also be taken.

After getting the required permissions, the recruitment process of participants will be started. The researcher will approach the participants in the NICU and neonatal step-down units. In addition, the researcher will

evaluate the participants based on eligibility criteria with the help of the patient's medical record numbers. After screening the relevant participants, the researcher will share the aim of the study with the participants. Moreover, the benefits of the study would also be explained. Upon willing agreement from the participants, written informed consent would be taken from them and the data collection process would then be initiated.

Study Variables

Dependent Variable

The dependent variable is the product variable, which is affected by the independent variable (6). Stress level among mothers with preterm infants is the dependent variable of the study. The stress among mothers is assessed through the PSS. The conceptual and operational definitions are as follows:

a. ***Conceptual Definition of Maternal Stress.*** Conceptually, maternal stress categorizes the delivery of a preterm infant and the consequences that are linked with this situation (12). Maternal stress is associated with multiple factors, which include the birth of a preterm infant, neonatal mortality, and LBW. Maternal stress increases if the emotional bond and support system are not available for the mothers (13). These factors amplify maternal stress, which lead to significant outcomes for the mother herself and her newborn.
b. ***Operational Definition of Maternal Stress.*** According to the operational definition, maternal stress in the study would be measured by the PSS. This scale measures the overall level of stress by encompassing the control over self and the conditions in life, personal confidence, and ability to control important aspects in life. The scores for the scale would be examined in the research study.

Independent Variables

The independent variable is the cause that itself cannot be changed but that will change the outcome of the study (6). The factors associated with the stress among mothers with preterm infants are taken as the independent variables in the study. The following are the independent variables of the study:

- Newborn's information.
- Mother's demographic data.
- Pregnancy-related variables.
- Family information.
- Coping mechanisms.

a. ***Conceptual Definition of Newborn Information.*** Respecting information related to the newborn is essential to identify the gestational age, as it depicts the LBW and prematurity status in the newborn. The demographics of the newborn, including prematurity, LBW, and neonatal infections, are pivotal factors that impact neonatal mortality in developing countries (14). These factors, including LBW and premature birth of the newborn are the prime aspects that potentially aggravate stress in mothers.

b. ***Operational Definition of Newborn Information.*** The newborn information included age, gender, date of birth, weight, height, presenting complaints, APGAR score, immunization status, the area from where the baby is transferred, and gestational age.
c. ***Conceptual Definition of Mother's Demographic Data .***The demographic data of the mother who delivers a preterm infant is of prime importance. Advanced maternal age at the time of birth is associated with an added risk of premature births (15). Furthermore, a study carried out in Milan, Italy, found that mothers of preterm infants frequently had low levels of education and were unemployed (15). Therefore, the demographic data including age, education status, and occupation of a mother is significant, as she is dealing with early labor and delivery of a preterm infant.
d. ***Operational Definition of Mother's Demographic Data.*** The demographic variables of the mother that are considered for the study included age, education status, occupation status, substance abuse, marital status, type of marriage, and number of years married.
e. ***Conceptual Definition of Pregnancy-Related Variables.*** Data related to previous pregnancies is of prime importance to rule out any risk associated with preterm birth. Maternal factors including parity, multiple pregnancies, PIH, APH, and PROM were correlated with the delivery of a preterm infant (16).
f. ***Operational Definition of Pregnancy-Related Variables.*** The variables related to pregnancy that are included in this study are gravida and parity of mother, number of children, mode of delivery, complications during pregnancy, co-morbidities, history of miscarriages, abortion, preterm births, and vaccination status.
g. ***Conceptual Definition of Family Information.*** A support system is a key factor that helps decrease stress and enhances the health of mothers with preterm infants. Good relationships with the husband, family care, and social support are significant in reducing the stress of the mothers and improving their emotional wellbeing at the same time (17).
h. ***Operational Definition of Family Information.*** This study included information about the type of family, co-morbidities, educational status of the husband, use of any substance by the husband, level of satisfaction from the husband, and in-laws. This identified the relationship with the partner and the extent of support being provided by the husband in the overall care of the mother and the newborn.
i. ***Conceptual Definition of Coping Mechanisms.*** Conceptually, mothers with preterm infants require and utilize various effective coping strategies to deal with stressful situations. Literature suggests that an individual practices similar coping strategies across various stressful conditions and the person only needs to boost up and recall the coping strategies to be used in different stressful situations (18). Coping-related

factors aid in determining the mother's coping mechanisms when handling stressful situations.

j. ***Operational Definition of Coping Mechanisms.*** Various coping strategies used by the mothers would be identified in the study. These included the ability to identify stress, modes of coping, modes of socialization, and the presence of a key person in times of stressful situations.

Data Collection Process

The process of data collection includes collecting information on subjects of interest, in an organized manner that assists the researcher to find answers to the study questions and assess outcomes (6). The participants will be assessed for eligibility by checking the medical records and matching them with the eligibility criteria. Ten participants would be recruited on a weekly basis from the neonatal step-down units and NICU, based on their availability.

The mothers' level of stress will be assessed through questionnaires. Each questionnaire would be completed in about 20-minutes. Both English and Urdu versions of the questionnaire would be made available to avoid any issues related to language. Moreover, factors related to pregnancy, family, and coping would also be explored. Upon identification of high levels of stress in mothers, it will be suggested to them to consult a psychologist to reduce the level of stress and maintain sound mental health to overcome the difficult situation. Necessary information about consulting a psychologist at the Aga Khan University Hospital would be provided upon request. Moreover, the importance of meeting a psychologist in a stressful condition would also be explained.

Data Collection Tool

Data collection tools must be validated by the researcher prior to their use to check for appropriateness in a particular context to minimize any bias (19). An internally developed questionnaire would use for the data collection. This tool includes components regarding demographic data for mothers and newborns. Moreover, pregnancy, family, and coping-related variables is also included. Furthermore, the PSS is also integrated into the questionnaire.

The study specific tool is run through a content validity index (CVI) where four experts in the concerned field were approached. All experts gave their marks out of 4 for each question in the questionnaire, for relevance and clarity, simultaneously. Each item was marked from 1 to 4 from 1 being not relevant and not clear, to 4 being very relevant and very clear. Upon their marking, the results were combined, the relevance came out to be 0.86 and clarity came out to be 0.92 which is considered satisfactory.

The PSS is a widely used functional tool for assessing stress among people going through difficult circumstances. This tool has been validated in the Pakistani context for assessing the level of stress among individuals (20). This tool consists of 10 items, in which participants give a

rating with regard to their emotions and mindset related to the events and circumstances that happened in the last month. Each item is rated on a 5-point Likert scale, from 0 never to 4 very often. Six items are negative (1, 2, 3, 6, 9, 10) and the other four are positive (4, 5, 7, 8). To create the score, the four positive items are scored in a reversed manner and then all the items are added, ranging from 0 to 40. This scoring included three levels, 0 - 13 low stress, 14 - 26 moderate stress and 27 - 40 is considered high perceived stress (21). To confirm, a higher score represents an elevated level of stress.

Internal Consistency

The internal consistency of the measuring tool is determined by the association of all items developed for measurement in the tool (22). The internal consistency of the tool is measured with Cronbach's alpha. The Cronbach's alpha value is 0.87 for the total perceived stress score. This value shows that the internal consistency of the tool is acceptable (Siqueira Reis et al., 2016).

Construct Validity

Validity reflects that the assessing tool measures the attributes it is projected to measure (22). The construct validity of the tool is measured, and the factor structure is assessed to observe whether the association between different variables in the tool is measuring a particular construct in the tool or not. The test-retest reliability score (r) is 0.86 for the total perceived stress score (23). This value depicts a satisfactory construct validity of the tool.

Study Rigor

Rigor in quantitative studies is determined through the tool's validity and reliability. Moreover, the test-retest reliability of a tool portrays the steadiness of the findings achieved, when the measuring tool is used for a similar group at separate periods of time (22). A pretesting of 10% of the sample would be done to observe the transparency of the tool that would be used in the study. The findings of the pretesting would be considered, and changes would be made accordingly, before conducting the actual research.

Data collection, analysis, data entry, and interpretation will be done by the primary investigator to reduce the chances of any type of error. In addition, the sample size considered for the study is large enough to augment the power of the study. Moreover, data gathered in quantitative research produces factual and accurate information, as it is assembled through systematized methods that can be recreated (22).

Data Analysis Plan

Analysis of the data will be done on the statistical package for social sciences (PSPP). Descriptive analysis and inferential analysis of the data will be considered in the study.

Descriptive Analysis

Descriptive analysis is a method used for portraying the data in a comprehensive manner, such that it examines the styles

and connections between the data in the research study (6). Demographic variables of the study, including categorical data, frequencies, and proportions, would be analyzed using descriptive analysis. Data that will be continuous in nature would be computed by measuring the mean and standard deviation. The level of stress among mothers with preterm infants, assessed through the questionnaire is categorical in nature, and would be reported through frequencies and percentage.

Inferential Analysis

The inferential analysis is utilized to determine the consistency of outcomes regarding a population, based on the data collected from the sample in the research study (6). Inferential analysis of the study findings would be carried out firstly by differentiating categorical variables and continuous variables. Analysis will further continued by using the chi-square test for the categorical variables and T-test for two independent samples for continuous variables in the study. During the analysis, the confidence interval of 95% and p-value of less than 0.05 would be considered as significant.

Ethical Consideration

Ethical considerations would be of prime importance throughout the research process. The study will be started after obtaining approvals from the CMO, and ERC of Aga Khan University Hospital (AKUH). Firstly, consent of the participants would be taken into account by thoroughly explaining the purpose, benefits and risk of the study. Moreover, participants would be given explanation about their autonomy to back out from the study at any point in time before the data coding is done. In addition, informed consent would be given in both English and Urdu languages for the understandability of the process to the participants. Furthermore, privacy would be considered as important and survey would be conducted in separate rooms. Lastly, confidentiality of data and patient identity would be assured.

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