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Effects of a Quiet Time Protocol Implementation on Respiratory Rate and SpO_2 in Preterm Infants

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Abstract

Background: There are extremely stressful stimuli in the NICU environment. Although attempts have already saved neonates in this unit, this can disturb the adaptability of the infants with environmental stimuli.
Methods: In this study, 120 preterm infants were randomly divided into experimental and control groups. The quiet time protocol was implemented at 16:00 - 18:00 while the control group received a routine program at 11:00 - 13:00. SpO_2 and respiratory rate were measured in 15-min intervals and one hour before and after both times. The sound level and light intensity were also measured. Data analysis was done by independent *t*-test, Mann Whitney, and ANOVA using SPSS version 11.5.
Results: Of all infants, 40% were girls and 60% were boys. Regarding intra-group comparison, the Friedman's nonparametric test showed that the percentage of oxygen saturation in the quiet-time group was not significantly different at the first, second, and third hours during the intervention ($P = 0.32$); in the control group, it was not also significant. The respiratory rate at the second hour of the intervention was lower in the quiet time group than in the control group ($P < 0.07$).
Conclusions: The implementation of the quiet time protocol can decrease heart rate and respiratory rate through a decrease in environmental stimuli (noise, light, and infant handling), and thus, is recommended for reducing stress in preterm infants.

Keywords: SpO_2, Respiratory Rate, Preterm Infant, NICU

1. Background

Approximately, 13 million preterm infants are born worldwide annually (1). Despite advances in obstetric care, not only the rate of preterm birth in recent 40 years has not decreased, but also it has increased in the past two decades (2, 3). Iran is also a region with a high prevalence of preterm delivery and premature infants, accounting for almost 10% of the total births (4).

Today, with the improvement achieved in the care of premature infants, especially with the proper use of surfactants, the number of premature infants who survive has significantly increased. This has turned the attention of experts to the improvement and development of this population (5). According to the WHO definition, the infants born earlier than 37 weeks from the mother's last menstrual period are considered premature (6). The premature infants, instead of being placed in a quiet environment and rich of sensory stimulation needed for their growth and development, are kept in the neonatal intensive care unit (NICU) where it is full of light, noise, and stress for the premature infant (7, 8).

Sources of stress in the NICU are disturbing and painful: long-term ventilation, nursing care, and physical environment, especially noise and light. In this condition, the infant has to consume its energy that may affect improvement and growth and change the physiological process and the structure of the central nervous system (9).

Noise is a very stressful environmental stimulus whose effects are reversible in short-term, but can also cause permanent long-term damage (10). America Pediatrics Academy recommends a moderate intensity of sound in the ward as 45 dB during the day and 35 dB at night (11). This level of noise in the NICU is due to incubators' fan, ventilator, other babies crying, and the noise of personnel, phones, and regular alarm of systems that can produce a noise up to 80 - 90 dB even inside the incubator (12). If the noise level is higher than the recommended levels, it may have adverse effects including reduced arterial saturation, increased heart rate and respiratory rate (13), hypertension

(14), and intracranial pressure. The prematurity of the self-regulation system of brain vessels in the infant indirectly causes decreased perfusion and oxygen supply to the brain and leads to agitation, crying, and behavioral changes (15, 16).

Another stressor in the ward is the early, prolonged exposure to severe light or continuous exposure to mild light, which can be harmful to preterm infants (17). The results of a study showed that the mean intensity of light in NICUs is about 300 lux that may reach the maximum intensity of 2251 lux (18). Some effects of severe light in preterm infants are retinal damage and impaired sleep patterns, the evolution of circadian rhythm, and growth (19). The results of studies on the infants' responses to light suggest that decreased light in the ward results in improved sleep, reduced physical activity, reduced heart rate, reduced fluctuations in blood pressure, and increased weight gain in infants confirmed with clinical status (20).

In neonatal wards, the infants' rest is usually impaired due to the repeated handling that is associated with physiological adverse effects such as hypoxia, apnea, hyperventilation, increased intracranial pressure, and behavioral disorders (21). To avoid disturbing the infant several times during a single hour (once for nutrition, then for the blood test, another time for removing or sucking the lung secretions), all these measures can be summed up and performed at the same time or shortly after another (22).

The environment we provide for the infant should not merely be considered for the survival of the newborn; but it has to include attention to the growth and development of the infant, too (12). Therefore, nowadays attention to various environmental stimuli and special conditions of NICUs, especially for premature infants, and painful procedures performed every day on these babies is of great importance. While exposure to strong stimuli such as light, sound, touch, or painful treatment procedures in the NICU can cause impaired brain development in newborns (23) in the short terms, it can interfere the infant's development process in the long term (24). Due to the physiological limitations of premature infants, the appropriate modification of the physical environment is necessary for the newborn's continued development and reduced length of stay in the NICU (25).

Another point to mention is the fact that nurses have the most contact with infants. This makes their roles important in the formation and modification of the environment. Thus, one of their duties in the ward is to deal with the stress of the physical environment, to evaluate its complications in the infant's health, and trying to solve the stress (26). This is possible when all personnel are aware of the effects of such stimuli. Infants reveal signs through changes in their physiological status such as changes in heart rate, respiration, oxygen level, blood pressure, skin color and temperature, and the way of coping with the environment (27).

Because of the effects of environmental stimuli on the infant and the lack of research in this field in Iran, the researchers decided to change the physical environment of NICUs for the growth and development of the infant through minimizing environmental stresses such as sound, light, and nursing interventions. Some of these changes included the implementation of a comfortable and costless method such as the quiet time protocol with the purpose of having one hour of uninterrupted rest during the day with reduced noise, light, and infant handling (28).

Some studies have shown that the quiet time has a positive impact on the infants. In fact, the aim of the quiet time is to improve the growth and development of infants in the NICU (29). Research has shown that the implementation of quiet time in the patient care unit promotes the relaxation and sedation for patients, families, and the staff by reducing the environmental noise and stimuli (30). With regard to the problems of environmental stimuli in the ward, we need such a protocol.

2. Objectives

The aim is to include it as a hospital standard, such as that of hand washing, in the program of improving the quality of the hospitals in the country, if positive results are obtained. The next aim is to evaluate the effect of the implementation of this protocol on SpO_2 and respiratory rate of premature infants.

3. Methods

This study was a clinical trial with a crossover design performed from March to June 2013. The population of the study consisted of preterm infants admitted to the NICU of Ghaem Hospital, Mashhad. The infants were enrolled according to the information available in their records. Given that the main variables in this study (respiratory rate and heart rate) were quantitative, determining the sample size was based on the comparison of the two communities. First, a pilot study was conducted and its findings were used to calculate the total sample size of the study. Finally, 120 cases (60 cases in each group) were calculated. Preterm infants were selected by a convenience sampling and divided randomly into two groups.

The inclusion criteria for infants comprised a gestational age of 30 - 37 weeks at birth, Apgar score $\geq$ 7 in the first and fifth minutes of birth, hemodynamic stability (HR

=120 - 160, RR = 30 - 50, SpO_2 = 85% - 95%, and the armpit temperature of 36°C - 37°C), spontaneous ventilation without other modes of ventilation, and lack of congenital malformations, particularly cardiovascular and respiratory diseases.

The exclusion criteria included the need for ventilation support during the study, being complicated with apnea and seizures during the study, and if other infants in the unit needed mechanical ventilation during the implementation of the quiet time protocol leading to the increased level of noise more than permitted (> 60 dB).

The content validity was used to determine the validity of checklists and forms used for selecting the sample, assessment of physiological indices and environmental stimuli in the unit, and the infant's demographic information. The validity of monitor devices, sound analyzer, and lux meter was determined based on valid marks under the supervision of experts. The simultaneous observation method was used to determine the reliability of the form used for recording the respiratory rate and heart rate of infants. In this method, the respiratory rate and heart rate of 10 infants were collected from the monitor separately by two nurses and then, by conducting a correlation coefficient test, the reliability was obtained as 0.96 and 98%, respectively. Moreover, the reliability equivalent was used to assess the reliability of the monitor, sound analyzer, and lux meter so that each time before the intervention, their accuracy was compared with another device. The light intensity was measured using a lux meter (Hagner model EC1) and the noise level using a sound analyzer (TES-1358 model).

Before the intervention, the researcher in a period of one week assessed the status of the ward in terms of relaxation time and environmental stimuli such as noise, light, and infant handling by nurses. Then, a training class was held for nurses in two days for two hours regarding the effect of the environmental stimuli on infant and the strategies to reduce these stimuli.

In the implementation phase of the plan, the quiet time protocol was performed every day by providing a checklist including three steps of adjustment of nursing activities, preparing the environment, and adjustment of mothers' activities in the presence and supervision of the researcher in the intervention group from 4 P.M. to 6 P.M.

The protocol was designed by the researcher based on the literature and surveys of professors and experts working in the NICUs. It included the reduction of environmental stress by adjusting the light intensity, reducing the ward's noise, limiting visits during the quiet time, and limiting the movements of employees. The treatment measures were performed as far as possible form this time (before or after) and if necessary, were performed as quiet.

In this study, the hours of 11 A.M. to 1 P.M. were considered as the normal time during which the control group received the ward's routine programs and no intervention was performed. The quiet time protocol was performed on the infants from 4 P.M. to 6 P.M. in the intervention group. The reason for choosing the time of 4 P.M. to 6 P.M. was that in these hours of the day, the lowest routine drugs were given and no visitor was present.

The sampling method was as crossover so that among the eligible infants, half of them were randomly placed in the control at 11 A.M. to 1 P.M. and the remaining in the intervention group in the quiet hours of 4 P.M. to 6 P.M. On the next day, the infants in the intervention group were placed in the control group and the infants in the control group were placed in the intervention group. For example, on the first day, the control group at 11 A.M. to 1 P.M. (normal time) and the intervention group at 4 P.M. to 6 P.M. (quiet time) were assessed in terms of heart rate and respiratory rate. On the next day, the same infants in the intervention group were assessed at 11 A.M. to 1 P.M. and the infants in the control group at 4 P.M. to 6 P.M.

Despite that infants in the control group apparently underwent the intervention of the quiet time, they were not evaluated for physiological variables at that time and moreover, the effects and outcomes of the intervention (the quiet time) were short enough to have no effect on the infant's status on the next day and hence, it had no confounding effect on the results.

Each infant was assessed for two hours during the normal time and the quiet time in terms of SpO_2 and respiratory rate using a monitor attached to the infant in the beginning of the intervention, every 15 minutes during the intervention, and one hour before and after the normal time and the quiet time. During the normal time and the quiet time, environmental stimuli such as light and sound levels were also measured.

In terms of ethical considerations, after receiving permission from the Ethics Committee of Mashhad University of Medical Sciences and offering the introduction letter from the School of Nursing and Midwifery to the Research and Treatment Education Center of Ghaem Hospital and obtaining informed consent from the parents of infants participated in the study, the objectives and relevance of the study were completely described for them. Parents were assured that participation in the study was voluntary and had no negative effects on service and care delivery of their infant, and information would be kept confidential. If the parents would like to participate in the study, a consent form was given to them to read and sign. The parents were encouraged to ask their questions from the researcher.

Data were analyzed using SPSS version 11.5 software.

To evaluate the normal distribution of quantitative variables, the Kolmogorov-Smirnov test and the Shapiro Wilk test were used. To compare the variables between the two groups in case of normal distribution, independent *t*-test and otherwise, Mann-Whitney test was used. To compare the intergroup related variables before the intervention, the first, and the second hour of the intervention, variance analysis with repeated measurements was used and in case of non-normal distribution, the Friedman test was performed. $P < 0.05$ was considered significant.

4. Results

In this study, there were 48 female infants (40%) and 72 male infants (60%). The mean gestational age of studied preterm infants was 32.0 ± 1.9 weeks and the age of infants at the time of the study was 6.1 ± 5.5 days. The mean birth weight was 1691.2 ± 55.06 g. In addition, 80% of the infants were hospitalized due to prematurity. The results in Table 1 show that the two groups of the normal time and the quiet time were significantly different in terms of exposure to environmental stimuli in the ward (sound, light, and infant handling) ($P < 0.001$).

According to the results in Table 2, based on the independent *t*-test, the two groups were not significantly different in terms of the respiratory rate before the intervention ($P = 0.49$), at the first hour of the intervention ($P = 0.23$), and after the intervention ($P = 0.26$). However, the respiratory rate at the second hour of the intervention was significantly different between the two groups ($P < 0.001$) so that the mean respiratory rate at the second hour during the intervention was about 10.8% lower in the group of quiet time than in the group of the normal time.

The internal results of variance analysis with repeated measurements showed that the respiratory rate significantly changed in the group of quiet time before the intervention, at the first and second hours during the intervention ($P < 0.001$); but these changes were not significant in the control group ($P = 0.12$). In terms of intergroup comparison, the general linear model of bilateral variance analysis suggested that the changes in the respiratory rate were not significantly different between the two groups ($P < 0.07$).

According to the results, the two groups had no significant difference in the percentage of oxygen saturation in the pre-intervention stage based on the results of independent *t*-test ($P = 0.12$) and they were homogeneous in this regard. Moreover, during the first and second intervention periods and after the intervention, the percentage of oxygen saturation in the two groups did not differ significantly ($P = 0.48$, $P = 0.99$, and $P = 0.49$, respectively). However, the mean oxygen saturation in the first and second hours of the intervention was less variable in the quiet time group than in the normal time group (Table 3). Regarding the intra-group comparison, the Friedman nonparametric test showed that the percentage of oxygen saturation in the quiet-time group was not significantly changed during the first, second, and third hours of the intervention ($P = 0.32$); in the control group, it was not also significant ($P = 0.40$).

5. Discussion

According to the results of this study, during the quiet time, environmental stimuli (noise, light, and infant handling) showed significant changes compared to the normal time ($P < 0.001$).

In terms of heart rate, the results of the present study showed that the mean heart rate of infants in the intervention group in the second hour during the study was significantly lower, about 10 beats/minute in infants of the control group. The heart rate in the group of the quiet time before the intervention, at the first and second hours of the intervention significantly changed, but the changes were not significant in the group of the normal time. The changes in the heart rate at different stages of evaluation were significantly different between the two groups.

The findings also exhibited that the two groups were significantly different in terms of the respiratory rate at the second hour of the intervention so that the mean respiratory rate at the second hour of the intervention was about six units lower in the quiet time than in the normal time groups. The respiratory rate in the group of the quiet time, before the intervention, at the first and second hours of the intervention had significant changes, but the changes were not significant in the group of normal time and between the two groups at different stages of evaluation.

This showed that the implementation of the quiet time protocol could reduce environmental stress (noise, light, and infant handling) and ultimately led to reduced heart rate in preterm infants. It seemed that the designed quiet time protocol in the NICU could be useful to lessen the responses to stress in preterm infants.

Slevin et al. performed a study entitled "Changing NICU and measurement of infants' responses". The results showed that during the quiet time, environmental parameters (light, noise, personnel's activities, and infant handling) had significant changes compared to the normal time ($P < 0.01$), and these changes in the NICU environment were significantly different in the quiet time period by a 2 mmHg decrease in diastolic blood pressure, mean arterial pressure, and decreased body movements. No significant changes were observed in terms of heart rate, systolic blood pressure, and blood oxygen saturation (31). In the

Table 1. Comparison of Environmental Stimuli in the Ward (Sound, Light, and Infant Handling) in the Two Groups of Quiet Time and Normal Time

Groups	Noise (dB)	Light (Lux)	Infant Handling (Frequency)
Quiet time	57.6 ± 1.5	72.3 ± 383.3	0.7 ± 0.5
Normal time	66.1 ± 2.6	759.9 ± 2.6	1.4 ± 5.2
P value[a]	$t = 21.84$, $P < 0.001$[b]	$z = 9.79$, $P < 0.001$[c]	$z = 9.55$, $P < 0.001$[c]

[a] Result of Mann-Whitney and independent-samples *t*-test.
[b] Independent-samples *t*-test.
[c] Mann-Whitney.

Table 2. Comparison of the Respiratory Rate Before, During, and After the Intervention in Two Groups of Quiet Time and Normal Time

Groups	Respiratory Rate (Mean ± SD)			P Value[a]	
	Before the Intervention	The First Hour During the Intervention	The Second Hour During the Intervention	Inter Group	Between Group
Quiet time	55.0 ± 7.4	52.5 ± 6.7	50.6 ± 6.9	< 0.001	
Normal time	53.9 ± 8.3	54.1 ± 8.2	56.1 ± 9.1	0.12	0.07
P value[b]	$t = 0.68$, $P = 0.49$	$t = 1.18$, $P = 0.23$	$t = 3.49$, $P < 0.001$		

[a] Result of analysis of variance with repeated measurements.
[b] Result of independent-samples *t*-test.

Table 3. Comparison of the Percentage of Oxygen Saturation Before, During, and After the Intervention in the Two Groups of Quiet Time and Normal Time

Groups	Percentage of Oxygen Saturation (Mean ± SD)			Friedman Analysis		After the Intervention
	Before	The First Hour During the Intervention	The Second Hour During the Intervention	Inter Group	Chi-Square	
Quiet time	94.5 ± 3.3	94.7 ± 3.0	94.9 ± 2.9	$P = 0.32$	2.26	94.8 ± 2.7
Normal time	95.5 ± 2.3	95.0 ± 2.6	94.0 ± 2.8	$P = 0.40$	1.83	95.53 ± 1.8
P value[a]	$z = 1.55$, $P = 0.12$	$t = 0.70$, $P = 0.48$	$t = 0.08$, $P = 0.93$			$z = 0.68$, $P = 0.49$

[a] Independent-samples *t*-test and Mann-Whitney

present study, during the quiet time, environment parameters (noise, light, and infant handling) were significantly reduced. In addition, during the quiet time, the heart rate and respiratory rate were significantly different. However, only was the heart rate significantly different between the two groups of the normal and quiet time. The heart rate and respiratory rate before, at the first and second hours of intervention reduced in the quiet time compared to the normal time.

The findings of Slevin et al. (31) study were inconsistent with the findings of the present study. In the study of Slevin et al., among physiological indicators, only was diastolic blood pressure significantly different in the quiet time so that diastolic blood pressure was 2 mmHg lower in the quiet time group compared to the normal time group. While in the present study, the implementation of the quiet time protocol could reduce the heart rate and respiratory rate, only was the heart rate significantly different between the quiet and normal time so that the heart rate was 10 beats/minute and the respiratory rate was about five units lower in the infants of the quiet time group than in those of the normal time group.

The difference in the findings of our study and Slevin et al. (31) study might be due to the quality of implementation of the quiet time protocol, short duration of the intervention, and different gestational age. In the study of Slevin et al., the implementation of the quiet time protocol lasted one hour from 2:30 P.M. to 3:30 P.M. while in the present study, it was for two hours from 4 P.M. to 6 P.M. Possibly the longer implementation of the quiet time protocol in the present study had more effects on the respiratory and heart rate. Further, in the study of Slevin et al., the studied preterm infants were with respiratory distress syndrome under mechanical ventilation with a gestational age of 24 - 32 weeks. However, in the present study, the preterm infants with a gestational age of 30 - 37 weeks were evaluated without mechanical ventilation.

Abujarir et al. performed a study entitled "The effect of earmuff on vital signs of newborns admitted to the NICU". The results showed that the heart rate, systolic

blood pressure, respiratory rate, and blood oxygen saturation were significantly changed within 72 hours in the group with earmuff compared to the group without earmuff ($P < 0.001$) (32). The findings of Shiroiwa et al. study showed that when the infants' eyes were closed, they had less activity and respiratory rate than the time their eyes were open (33).

In the studies of Abujarir et al. (32) and Shiroiwa et al. (33), the results showed that the vital signs were stable when environmental stress was reduced through using earmuff and blindfold, which was consistent with the present study findings. In the mentioned studies, although earmuff and blindfold could be stressors in preterm infants, using them was effective and the results were positive. This is while in the present study, by the implementation of a quiet time protocol including environmental and behavioral changes of the personnel of the NICU during a given period of the day without any stress for the infant, environmental stress was decreased and led to decreased heart and respiratory rate in preterm infants.

The limitations of this study included different thresholds of pain in the infants and individuals and differences of infants in response to external stimuli. We tried to decrease the severity of these effects by random assignment of the infants into two groups of the quiet and normal time.

5.1. Conclusions

The overall goal of this study was to determine the effects of a quiet time protocol on respiratory and heart rate in premature infants. The results showed that the heart rate decreased with the implementation of the quiet time protocol. Due to the effectiveness of the quiet time protocol in the reduction of environmental stimuli through behavioral and environmental changes, it is recommended to implement this protocol as the standard care for reducing stress and improving the growth and development of premature infants in the NICU. Given that one of the main responsibilities of nurses is to achieve non-invasive methods for the treatment and care of patients, it is hoped that the results of this research increase the area of nurses' activities related to the care of premature infants and enhance the quality of nursing care. It is suggested that the quiet time protocol is assessed in longer periods (morning, afternoon, and evening shifts) in future studies.

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Footnotes

Clinical Trial Registration: The research project was approved by Mashhad University of Medical Sciences with the code of IR.MUMS.921564 and IRCT code of 2013082414454N1.

Conflict of Interests: No conflict of interest is reported.

Ethical Considerations: In terms of ethical considerations, after receiving permission from the Ethics Committee of Mashhad University of Medical Sciences and offering the introduction letter from the School of Nursing and Midwifery to the Research and Treatment Education Center of Ghaem hospital and obtaining informed consent from the parents of infants participated in the study, the objectives and relevance of the study were completely described for them. The parents were assured that participation in the study was voluntary and had no negative effects on service and care delivery of their infant, and the information would be kept confidential. If the parents would like to participate in the study, the consent form was given to them to read and sign. The parents were encouraged to ask their questions from the researcher.

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