Investigating the Effect of Fetal Position on the Sleep-Wake State of Premature Neonates in the Neonatal Intensive Care Unit: A clinical trial study

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Background: One of the factors affecting the developmental and cognitive course of premature neonates is their sleep-wake state. Therefore, this study has been conducted with the aim of investigating the effect of fetal position on the sleep-wake state of premature neonates hospitalized in neonatal intensive care unit. Method: the present clinical trial study was conducted on 90 premature neonates hospitalized in NICU of Aliebne Abitalab Hospital in Zadehdan in 2017. The data were collected through demographic information questionnaire and Als sleep-wake behavior scale. Furthermore, Friedman statistical test was used to determine the relationship before, during, and after the intervention in the stages of the study. Results: in this study, the maximum percentage and average time of sleeping in fetal position was related to deep sleep. Further, this position decreased the frequency and duration of light sleep, drowsiness, active wakefulness, and crying in premature neonates. However, it did not affect the duration of slow wake state in these neonates. Conclusion: the state of sleep-wake in premature neonates is very important, and if neglected it can result in developmental and cognitive complications in this group of sensitive neonates. Therefore, this crucial issue requires further studies. On the other hand, regarding the factors affecting the sleep-wake state of neonates including the effect of position, further studies should be conducted in order to provide the results of these studies for medical and nursing teams and minimize the developmental and cognitive complications resulting from sleep disorders in premature neonates.

INTRODUCTION
One of the most important health indicators of any country is neonatal mortality (1). Today, with the advance of science and technology in early diagnosis of problems of premature neonates and through timely intervention, the chance of their survival has increased (2). In parallel to the increase in the survival premature and low birth weight neonates, the extent of developmental pathologies is increasing. Disorders in cognitive development and function as well as neurosensory problems are observed in many premature infants (3). Therefore, performing special clinical interventions to reduce the stress of neonates hospitalized in NICU should be one of the healthcare priorities (4). Premature neonates, during their hospitalization in the NICU, are at the stage of rapid brain development. Therefore, paying attention to neonatal sleep care in NICU is crucial in improving the quality of care from these sensitive neonates (5, 6).

Proper development of sleep-wake states is significant for premature neonates (7). Many studies have shown that disorders in sleep-wake states of premature neonates result in various complications (8) including diminished brain mass (9), reduced pain threshold (10), increased sensitivity to diseases (11), impaired primary development of senses, consciousness disorders, cognitive disorders, physiological disorders (12), impaired psychosocial development, increased chance for attention deficit disorder diagnosis (13), and infantile sudden death syndrome (14). The results of the study by Bastani et al., indicated that the sleep-wake state of premature neonates in NICU has an undesirable state (15).

One of the early developmental interventions in the neonatal ward which causes sleep improvement is positioning the neonate. Premature neonates have a week muscle tone (16). Positioning the neonate results in improved growth and development, prevention from involuntary muscular spasm, reduction of energy consumption, decrease in stress, and development of self-relaxation of the neonate (16). Keeping the body posture in fetal or bent position is the best position for a premature neonate. In the uterus, the hands and legs are bent and approach each other, while the head lies in the middle in a neutral position. Uterus, as a wall, controls the erecting movements of the trunk and limbs, and helps in keeping fetal position. Therefore, maintaining and keeping this position after the birth of a premature neonate is essential (17). However, this issue is often neglected in neonatal wards. The study by Visscher et al. (2015) indicated that the total sleep time is longer in fetal position than in other positions (18). Further, in another study by Lcania
et al it was found that the wakefulness time in fetal position is shorter, while the active and slow sleep in this position is longer. Further, in this study, by investigating the behavior of premature neonates it was found that different types of wakefulness and perturbation are less frequent in fetal position (19).

Considering the increase in the number of preterm labors and the need for long-term hospitalization of these neonates, it is necessary to provide care which in addition to shortening the hospitalization duration, they should be harmless and economical and easily implementable in wards. The relationship between neonatal sleep and long-term consequences and their quality of life in the future highlights the role of nurses in supporting and improving the sleep of hospitalized neonates. Therefore, all care providers especially nurses which are in direct contact with neonates should make attempt to improve and prolong the duration of this group of delicate and sensitive patients. Therefore, this study has been conducted with the aim of investigating the effect of fetal position on the sleep-wake state of premature neonates.

**METHODS**

**Design and participants**

The present clinical trial study was conducted on 90 premature neonates specialized in NICU ward of Ahliffe Abitalab Hospital in Zahdan City in 2017. The inclusion criteria were: gestation weeks less than 37, being hospitalized in NICU ward, birth weight of 1200-2500 g, written consent form signed by parents, no addiction on the part of mother, not using drugs of abuse and sedatives, absence of chest tube and umbilical catheter, and no intra-ventricular hemorrhage (IVH).

**Data Collection Instrument**

The data were collected using demographic information questionnaire (the type of delivery, pregnancy age, birth weight, and Apagar score minute (4, 20), and also sleep-wake scale. In this instrument, totally, six sleep-wake states have been defined for premature neonates including deep sleep, light sleep, drowsiness, slow wake, active, wake, and crying. Each of these states is defined based on its special behavioral and physiological properties including breathing regularity, presence or absence of rapid eye movements, openness or closure of eyes, facial manifestations, body movements, skin color, oral movements, etc. In this instrument, a table with 30 columns and 4 rows has been designed. The rows include the six sleep-wake states, while the columns of the present duration of the study with 2-min intervals. The observer should observe the behavior of the neonate every two minutes, identify their position, and record it. In this table, the duration of a position is not recorded; rather the type of position the neonate adopts is important. This means that if a position lasts for 3 s while another lasts for 10s, both have the same degree of importance. Nevertheless, any sleep-wake state should last for at least 2-3 s, in order to be known as a position and be recorded. For statistical calculations of the data, only the rate of incidence of a state has been considered, and then percentage of incidence of each state in three stages before, during, and after the intervention has been calculated and then compared in the intervention and control groups.

HeidelisAls suggests that in order to use this instrument better, before any intervention for the neonate, their behaviors should be observed and recorded for at most 20 min. Then, during the intervention, the behaviors are observed and recorded, and after the intervention again the behaviors of the neonate are observed and recorded for at least 20 min (21). The validity of the mentioned instrument has been studied through content validity method based on the study by Rajaee in 2012 in cooperation with 10 faculty members of Tehran University of medical sciences (22). The validity of the translation of this instrument has also been examined by a neonatal subspecialist, and to determine the scientific reliability of instrument, first the researcher received the necessary training for using this instrument from its developer (HaedlisAls) through the Internet. Then, the researcher, alongside a trained nurse and in the form of a pilot study, investigated the sleep-wake behaviors of premature neonates hospitalized in neonatal care ward using this instrument. For the reliability of this plan, the researcher and the colleague trained nurse compared the results of their intervention in the pilot sample with each other in order to see whether the results of intervention by assessment of the two persons were congruent or not.

**Procedure of data collection**

For the research, after receiving permission from the faculty and ethics committee of Zahedan University of Medical Sciences, the researcher visited the hospital, presented the required explanations, acquired permission from the official of the ward, and eventually collected data.

The sampling method in this study was convenience sampling method. For this purpose, after presenting sufficient explanations to the mothers and receiving written consent form from them, the researcher chose the neonates of interest and evaluated. Before the sampling operation, in order to modify the confounding factors, the light cycle was done and level of noise was reduced (by placing a cover on the incubator and double-walled incubator, taking care of alarms and noises, and by conducting the study in the afternoon). In the next stage, the chosen neonates were studied randomly one time as the control group and another time as the test group, where every neonate was also considered as their control. In order to assign neonates as being control or test, in the first stage, drawing via random method was used, where A and B letters were written on two same-shaped and same-sized cards, and another colleague without previous awareness was requested to choose one of them. If in the first stage, Card A was chosen, then the neonate was first considered as the test and then as control. On the other hand, if Card B was chosen, it was vice versa. The studied neonates underwent the intervention for 5 h in the afternoon shift, and before the intervention, any measure of care required by the neonate was done by the ward nurse including nutrition (in case of not being NPO), changing diaper, administering medication, weighing, displacing the probes, etc. except for painful invasive measures such as venipuncture and blood sampling. The neonatal pain due to affecting the control sleep disorders, then thermal probe and monitor leads were connected to the baby (two leads on the armpit, one on the thigh, and the thermal probe on the newborns back on the liver region). In this way, the neonate was controlled in terms of physiological criteria along the study through Saadat monitoring, B9 model, so that if life-threatening conditions (apnea) were developed for the neonate, they would be excluded from the study.

Then, the researcher during the afternoon shift, following the proper principles of hand hygiene, positioned the studied neonates in the intervention group as relaxed and free in the nest, where anti-sensitivity fabrics were used based on the neonate size and as the bird nest prepared by the researcher in the form of fetal position (i.e. the neonate’s back was bent and was C-shaped, the legs were bent towards the belly, the hands were also bent and on the face region, where the neonate could freely put their hands into your mouth and achieve self-regulation. The lumbar arc of the neonate was lied down slowly by diaper or supported fabrics made of nest (the nest should be prepared such that the neonate
could beat their hands and feet to its wall so that their muscles would grow stronger. Also, these walls would evoke an environment such as the uterus wall for the neonate and the flex state of term neonates would be provided for the neonate). Then, the sleep of neonates was evaluated before, during, and after the intervention through the method explained further.

From 2-2:20 p.m. (the stage before the intervention), nor intervention was done on the baby, and only 20 minutes of the neonate’s sleep was recorded by the researcher. In the stage of intervention (2:20 – 4:30 p.m.), the first 30 minutes of the neonate’s sleep was considered as the base level, while the rest (from minutes 30 to 50); it was considered as the level of intervention. During these 20 minutes, the researcher directly observed the neonate once every two minutes and identified the sleep-wake state of the neonate (every state has its own set of special behaviors such as eye openness or closure, body movements, facial gestures, etc.) and recorded in the relevant table. After two 30-min periods, the studied neonates (after receiving routine cares such as replacing the site of probe and feeding) were placed in supine position by a trained nurse (while the neonate’s head was in the midline, their hands were retracted and their back got into contact with the bed). At this stage, no intervention was done on the neonate and only once every two minutes for 20 min, the neonate was examined by the researcher and the obtained data were recorded in the checklist of interest.

Ethical Considerations
Before the intervention, patients were asked for oral and written consent for participation in the study. This study was approved by the Ethics Committee of Zahedan University of Medical Sciences and the Ethics Committee of the place where research was conducted (Ethic code: 153.IR.ZAUMS.REC.1396). Clinical trial was approved by Iranian Registry of Clinical Trials (IRCT) under NO: IRCT20171007036599N3. The CONSORT checklist was used to report the study (23).

Data Analysis Method
In this study, for analyzing the data, IBM SPSS 16 software was used. In order to categorize and summarize the findings, descriptive statistics including absolute and relative frequency distribution tables were used, and for determining the relationship between before, during, and after the intervention across the studied stages, Friedman statistical test was used.

RESULTS
Out of the 90 premature neonates present in the research, 56.7% were boys and 43.3% were girls. Out of this number, 22.2% were born through natural labor method, while 77.8% were born through C-section. The mean Apgar minute 1 of these neonates was 6.77 with the standard deviation of 1.092. Further, their mean Apgar minute 5 was 9.11 with the standard deviation of 1.022. The mean pregnancy age of the mothers of these neonates was (3.62) (31.57 weeks). In addition, the mean weight of these children at the time of birth was (291.35) 1558.22 (Tables 1 and 2) (Figure 1 and Figure 2).

The frequency of deep and light sleep before the intervention was 3.3 and 60%, respectively. Based on the obtained information, during the intervention all neonates present in the research had a deep sleep of 84.4% and light sleep of 15.6%. It was found that after performing this intervention, these frequencies declined, such that 43.3% of these neonates had deep sleep and 38.9% had light sleep. According to the results obtained from Friedman analysis, to compare the sleep of these neonates before, during, and after the intervention, it was observed that this test was significant (P-value=<0.0001). In other words, it can be concluded that the sleep of neonates at the three times before, during, and after the intervention had a significant difference with each other. According to the descriptive information previously mentioned, during the intervention the sleep of most neonates was deep or light without any stress (Table 3).

Based on the information, the mean deep sleep of the neonates before the intervention, their mean light sleep, and their mean drowsiness have been 1.06 (2.87), 9.73 (6.25), and 6.11 (4.65), respectively. Note that during the intervention, the mean deep sleep increased to 14.02 (4.42) min. The mean light sleep during the intervention is 5.62 (4.1), while the mean drowsiness, non-REM sleep, active awakening, and cry of neonates during the intervention were either zero or very close to zero. After the intervention, the mean deep and light sleep values were 7.77 (6.11) and 7.84 (4.46), respectively. The results of repeated measurements analysis to compare the time of neonates’ sleep in the states of deep sleep, light sleep, drowsiness, active awakening, and crying before, during, and after the intervention have indicated a significant difference. However, this test did not become significant for slow wake state (P-value=0.274) (Table 4).

DISCUSSION
Various studies have been done on investigating the effect of different positions on the sleep of premature neonates. For example, in a study by Feldman et al, kangaroo care resulted in prolonged duration of slow sleep in neonates (24). Alternatively, Liaw et al., indicated that having the baby sleep to the side position leads to prolonged duration of slow sleep in them (25). Axelin et al., conducted a study on the effect of controlling pain on the sleep of premature neonates (26). Based on the results of this study, fetal position results in controlled pain and prolonged sleep of the neonates. In the recent study, the effect of fetal position has been examined on the sleep-wake state of premature neonates. The results of this study suggest that the longest mean sleep duration in the fetal position is related to deep sleep. Further, this position decreases the frequency and duration of light sleep, drowsiness, active wake, and crying in premature neonates. However, it does not affect the duration of slow wake, which is in line with the results of the study by Visscher et al. This study has been conducted in 2015 on 25 premature neonates as crossover. All of the neonates investigated in this study had nutritional problems such as abdominal distention, reflux, necrotizing enterocolitis, and bowel obstruction, while problems such as apnea, sleep problems, and orthopedic problems were not observed in them. On the other hand, these neonates did not receive mechanical ventilation and sedative drugs. In this study, after being fed and receiving other cares by a trained nurse, these neonates were transferred from one position (prone position) to the next position (fetal position), where parameters such as slow sleep, active sleep, waking time, and effective sleep have been measured in them. Based on the results of this study, the total sleep time is longer in fetal position than prone position (195 versus 169). Further, in the prone position, the waking time is shorter than the fetal position (39 versus 44). In this study, the extent of slow sleep was not significantly different between the two positions. EEG evaluation of the neonates in this study has indicated that effective and deep sleep is greater in fetal position, while waking time is shorter in this position (18). This intervention has been conducted in single rooms and on neonates with nutritional problems. However, the present study has been done under the conditions of wards in Iranian hospitals and on premature neonates without nutritional problems. Furthermore, this intervention has been done at the night shift, while the present study...
Table 1: The descriptive table of the qualitative demographic variables

<table>
<thead>
<tr>
<th>variable</th>
<th>Frequency (percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>(56.7)39</td>
</tr>
<tr>
<td>Female</td>
<td>(43.3)51</td>
</tr>
<tr>
<td>Type of labor</td>
<td></td>
</tr>
<tr>
<td>Natural</td>
<td>(22.2)20</td>
</tr>
<tr>
<td>C-section</td>
<td>(77.8)70</td>
</tr>
</tbody>
</table>

Figure 1. Gender of Participants

- Male: 57%
- Female: 43%

Figure 2. Type of labor among participants

- Natural: 78%
- C-section: 22%

Table 2: The descriptive table of the quantitative demographic variables

<table>
<thead>
<tr>
<th>variable</th>
<th>Mean</th>
<th>Maximum</th>
<th>Minimum</th>
<th>Standard deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-minute Apgar score</td>
<td>6.77</td>
<td>9</td>
<td>4</td>
<td>1.092</td>
</tr>
<tr>
<td>5-minute Apgar score</td>
<td>9.11</td>
<td>10</td>
<td>6</td>
<td>1.022</td>
</tr>
<tr>
<td>Gestational age</td>
<td>31.57</td>
<td>27</td>
<td>37</td>
<td>3.623</td>
</tr>
<tr>
<td>Weights during birth</td>
<td>1558.22</td>
<td>900</td>
<td>2100</td>
<td>291.35</td>
</tr>
</tbody>
</table>

Table 3: The frequency and percentage of frequency before, during, and after the intervention as well as comparing the frequency of six sleep states at these three times

<table>
<thead>
<tr>
<th>variable</th>
<th>Frequency before intervention (%)</th>
<th>Frequency during intervention (%)</th>
<th>Frequency after intervention (%)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sleep state</td>
<td>3(3.3)</td>
<td>76(84.4)</td>
<td>39(43.3)</td>
<td></td>
</tr>
<tr>
<td>Deep sleep</td>
<td>54(60)</td>
<td>14(15.6)</td>
<td>35(38.9)</td>
<td></td>
</tr>
<tr>
<td>Light sleep</td>
<td>17(18.9)</td>
<td>-</td>
<td>9(10)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>
has been conducted at the afternoon shift. Further, the findings obtained from this research are congruent with the results of the study by Lacina et al. This study which has been conducted in 2015 on 25 premature neonates as crossover suggests that the waking time is shorter in the fetal position, while the duration of active and slow sleep is greater in this position. All of the neonates investigated in this study first tolerated feeding and then were free from brain (IVH) and orthopedic problems. Furthermore, these neonates did not receive mechanical ventilation and sedatives. In this study, the effect of fetal and supine positions has been examined on the sleep of neonates during 24 hours. The position of the studied neonates was altered every three hours after feeding and receiving routine care by a trained nurse. The intervention was done once at the night shift and another time and the morning shift, and the sleep of neonates was examined for 30 min by a trained nurse with the criterion of DrAls and EEG. The results of this study indicated that the neonates have a shorter waking time in fetal position. Furthermore, in this position, slow wake, active wake, and crying of neonates are less, while the slow and deep sleep has been greater (19). When comparing these studies, the following points should be taken into account: 1) the intervention has been done in single rooms and on neonates with surgical problems. Developmental and cognitive complications of deep-sleep fetal position are: Cord prolapse; birth trauma as a result of extended arm or head, incomplete dilatation of the cervix; asphyxia from cord prolapse, cord compression, and placental detachment or arrested head (27, 28). However, the present study has been conducted under the conditions of wards in hospitals of Iran and on premature neonates without surgical problems; B) in this study, polysomnography and behavior observation methods have been used, but in the present study only behavior observation was used: C) the present study has considered a larger sample size.

Limitations
Limitations of present study were included: in this study, the sleep-wake state of neonates has been done only through observation of behavior. It is suggested that, in future EEG method be also used in order to compare the results. Also, the sleep-wake state of neonates with a fetal age below 29 weeks can also be examined.

CONCLUSION
The sleep wake state is very important in premature neonates, and if neglected it can cause incidence of developmental and cognitive complications in this group of sensitive neonates. All attempts of healthcare providers especially nurses who have the greatest contact with neonates should be directed towards improving and increasing the sleep duration of neonates. Therefore, this crucial issue requires further studies. Meanwhile, more estimation should be done about the factors affecting the sleep-wake state of neonates including the effect of position, in order to provide medical and nursing teams with the results obtained from these studies and minimize the developmental and cognitive complications resulting from sleep disorders in premature neonates.

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