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The Effect of Plastic Cover on Regulation of Vital Signs in Preterm Infants: A Randomized Cross-over Clinical Trial

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ABSTRACT

***Background*:** Considering the susceptibility of preterm infants to disturbances of vital signs, this study was conducted to investigate the effects of using plastic covers on regulation of vital signs in preterm neonates.
***Methods*:** This randomized, cross-over, clinical trial was carried out on 80 preterm infants admitted to neonatal intensive care unit (NICU) of Taleghani Hospital, Tabriz, Iran. The study was conducted in two days (on the second and third days of the infants' life). In group 1, plastic cover was used during the first day followed by the use of blanket on the second day, while the order was reversed in group 2. Digital thermometer was used to measure the infants' axillary temperature. Heart rate and oxygen saturation were measured through monitoring. To analyze the data, descriptive (Mean and SE, 95%CI) and inferential statistics (repeated measurement and ANCOVA tests) were used in SPSS version 13 and MiniTab software.
***Results*:** Fourteen infants who were covered with blanket were found to suffer from hypothermia, while no infant with a plastic cover encountered this problem. The percentage of arterial blood oxygen saturation in the group with plastic covers was higher, and as a result, the infants received less oxygen supplements. However, no statistically significant differences were observed in heart rate between the groups.
Conclusion: Use of plastic cover during NICU stay prevented hypothermia in premature infants, with the arterial blood oxygen saturation being within the normal limits. Yet, it did not seem to have a significant effect on other vital signs.

Keywords: Body temperature, HR, Neonatal intensive care unit, Polyethylene wrap, Preterm infants, SpO_2

Introduction

Preterm infants are born before their body and organ systems mature. Such infants are often small and extremely vulnerable and most of their body organs are not ready for extrauterine life; therefore, they might not function properly due to extreme immaturity (1).

Body function signs reflect infants' physiologic conditions and are regulated via homeostatic mechanisms. Body temperature, heart rate, and arterial blood oxygen saturation (SpO_2) are considered among such signs. Heart rate, which indicates the condition of blood circulation, is one of the basic vital signs in infants. All infants hospitalized in neonatal intensive care units (NICUs), who are physiologically unstable, must be monitored for vital signs, particularly heart rate (2). Evaluation of physiologic indices is performed by monitors that assess heart rate and SpO_2 level (1).

In infants who receive oxygen or have been under recent oxygen therapy, SpO_2 level must be constantly monitored. In order to maintain central temperature, infants show physiologic responses to temperature fluctuations such as bradycardia

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and hypoxia. Hypothermia is one of the most common problems in preterm infants during infancy (3). The infants with a birth weight of less than 1500 g are more susceptible to hypothermia (4). Hypothermia is one of the major factors contributing to neonatal mortality and high rate of side effects in infants (5). It is also one of the worldwide factors which endangers preterm infants' health (6).

Hypothermia is reported to underlie an increased mortality rate among the infants of virtually all age brackets admitted to NICU (7); it is an independent risk factor for mortality in infants (8). The rate of hypothermia in preterm infants at the time of birth is 42-73% (9-11), which requires more attention in developing countries (12). In Iran, the prevalence of hypothermia is 53.3% (13).

Although radiant heater facilitates access to the preterm infant, it causes water evaporation via skin, making the infant susceptible for dehydration. Plastic covers, which are easy to handle (14), were introduced to prevent heat loss in preterm infants (15). The use of plastic cover is considered one of the major interventions in the prevention of hypothermia in low birth weight preterm infants, as it brings about dehydration and heat loss through convection (16), and helps with infants' survival and body temperature maintenance. It is also beneficial in prompt recognition of bleeding in umbilical cord or and other parts of the body (17). Blankets, on the other hand, are used to keep the infants warm (18) and prevent heat loss via induction, radiation (14, 19-22), and evaporation (18).

Preterm infants generally receive care in a specific unit called Neonatal Intensive Care Unit (NICU). In NICUs, a large number of personnel participate in neonatal care. Nurses should recognize infants' potential risks and crucial conditions and take measures to lower those risks (1). Regulating infants' body temperature is one of the major responsibilities of nurses (23). Nursing interventions could play an important role in maintaining warm chain, recognizing problems at the right time, and taking prompt treatment steps to prevent relevant side effects (1). Monitoring vital signs of infants is a crucial nursing care (23). Therefore, nursing interventions are of key importance in regulating infants' vital signs, maintaining a warm chain, recognizing the problem at the right time, and taking instant interventions to prevent unwanted side effects (3).

In view of numerous treatment procedures, infants are usually placed under a radiant heater in Tabriz NICUs, as in other centers in Iran, to provide convenient access and easy observation. During the first days of hospitalization, a plastic tent is placed on an infant's whole body as well as the whole heater while it was hung from sides of the heater. The alternative way is to cover the infant with a blanket up to the shoulders, with the skull covered with a hat. Recently, Neonatal Individualized Developmental Care Program (NIDCP) has suggested that the use of any cover up to infant's shoulders makes the face obvious, thus, making it easy to be observed and monitored. Accordingly, it considers plastic tent as an obstacle in the way of the mother and infant establishing eye contact with each other.

Considering that plastic cover and blanket are both proven to be economical, easy, and safe ways of preventing hypothermia, and considering the paucity of studies on the effect of plastic covers on regulating infants' vital signs during NICU stay, we sought to investigate the effect of plastic covers on the regulation of vital signs in preterm infants who were under radiant heater in NICU of Taleghani Hospital of Tabriz, Iran. This study was carried out to investigate and apply the most preferred way of regulating infants' body temperature and other vital signs without obstructing mother-infant visual contact in accordance with NIDCAP.

Methods

This single-blind, randomized, cross-over clinical trial was carried out at Taleghani Teaching Hospital, in Tabriz, Iran, 2016. Having obtained written consent from the parents and permission from Ethics Committee of the university (code No.: TBZMED.REC.1394.846) and having registered the study in IRCT website with the code number of IRCT201407218315N11, we enrolled the qualified infants in the study in accordance with their admission order to NICU.

The inclusion criteria in the study were gestational age of 28-30 weeks (the gestational age was calculated and determined via ultrasound or the first day of the last menstrual period), birth weight of 800-1250 g, being two days old, being inborn, being nil per os, being admitted to NICU since the birth day, being nursed under similar radiant heater in Servo-control mode, and being under respiratory care

in Nasal Continues Positive Airway Pressure (N-CPAP) or High Flow Nasal Canola (HFNC) way. The infants suffering from spinal cord defects, congenital skin diseases, congenital heart diseases, omphalocele, gastroschisis, metabolic diseases, and sepsis were excluded from the study together with the ones under ventilation and phototherapy.

With the power of 0.8 and 95% confidence, and based on the results of similar studies (SD= 0.57, maximum α= 0.5) (24) and the pilot study, the sample size in each group was calculated as 35 infants, using the formula of comparing mean of two population. Considering 10% attrition, the sample size increased to 40 infants in each group and to 80 infants in total.

The neonates meeting the inclusion criteria were randomly allocated to two groups. The first case was chosen through simple random (draw/lottery) sampling and the next cases were allocated to each group alternately (ratio1:1). The study period in each group was two days. According to statistical accuracy, measurements must be made by a single person, but measurement over 24 hours a day for one person cannot be applicable. For this reason, body temperature, heart rate, and O_2 saturation in both groups were measured at 8:00, 9:00, 12:00, 15:00, 18:00, and 21:00 O'clock by one person. The main researcher performed the intervention and a single individual carried out all the measurements. The statistical advisor determined how to randomize to intervention and analyze the data. The statistical consultant was blind to the study intervention and had no information as to the advantages and disadvantages of plastic cover and blanket.

In group 1, the infants were covered with a sheet from 8:00 a.m. to 9:00 a.m. (to pass wash out time and remove the effect of the previous cover). At 9:00 a.m., the sheet was removed from over the infant's body. From 9:00 a.m. to 8:00 a.m. on the next day (i.e., for the next 23 hours), the infant was covered with a plastic cover up to his/her neck. On the second day of the intervention, the plastic cover was removed at 8:00 a.m. and until 9:00 a.m. (for 1 hour) the infant was covered with the sheet up to his/her neck (to pass wash out time and remove the effect of previous cover). Afterwards, the same infant's body (except for his/her head) was covered with blanket for 23 hours. The infant's head and face were out and head covered was with a hat.

In group 2, the procedure was almost the same as the group 1, the only difference being the covering of the infant's body with blanket during the first 24 hours and with the plastic cover during the second 24 hours. The infant's head and face were out and head covered with a hat.

Welch Allyn digital thermometer was used to measure the infants' axillary temperature. The preterm infants' normal body temperature was between 36.5°C and 37.5°C. The temperatures below 36.6°C and above 37.5°C were considered as hypothermia and hyperthermia, respectively (25, 26). The vital signs included the heart rate and oxygen saturation of arterial blood, which were measured through placing Masimo monitoring set (SAADAT company, Iran) on the infant's foot. The monitoring probe areas were changed every three hours.

The infants' normal heart rate was between 120 and 160 beats per minute. The rates below 100 and above 180 per minute were considered bradycardia and tachycardia, respectively (26, 27). The normal rate of oxygen saturation was 85-95%. The rates below 85% and above 95% were considered as hypoxia and hyperoxia, respectively (26). All the infants were cared for by a similar radiant heater model HKN-93B. The heater was in Servo-control mode. The study instruments were calibrated by the company engineers before the data was collected. To ensure that the measured values of temperature were reliable, the correlation between the recorded values of 10 infants was calculated and the coefficient was acceptable (r=0.96).

Data collection sheets were researcher-made. The demographic form included baby code, date, case number, date of birth, gender, weight, time of birth, gestational age, chronological age, and medical diagnosis. The vital signs (i.e., body temperature, heart rate, and oxygen saturation) were recorded in the table format with some more information such as heater, environmental heat, and moisture. Content validity of the data collection form was confirmed by seven professors of Faculty of Nursing and Midwifery and neonatologists from Tabriz University of Medical Sciences.

Before each body temperature control, the heater, environmental heat, and moisture were checked and the infants were examined for skin rash, allergy, hyperthermia, and skin changes. During temperature measurement, the cover was lowered to the infants' nipple line to make it possible for the thermometer to be put in the infants' armpit (the cover was not lowered below

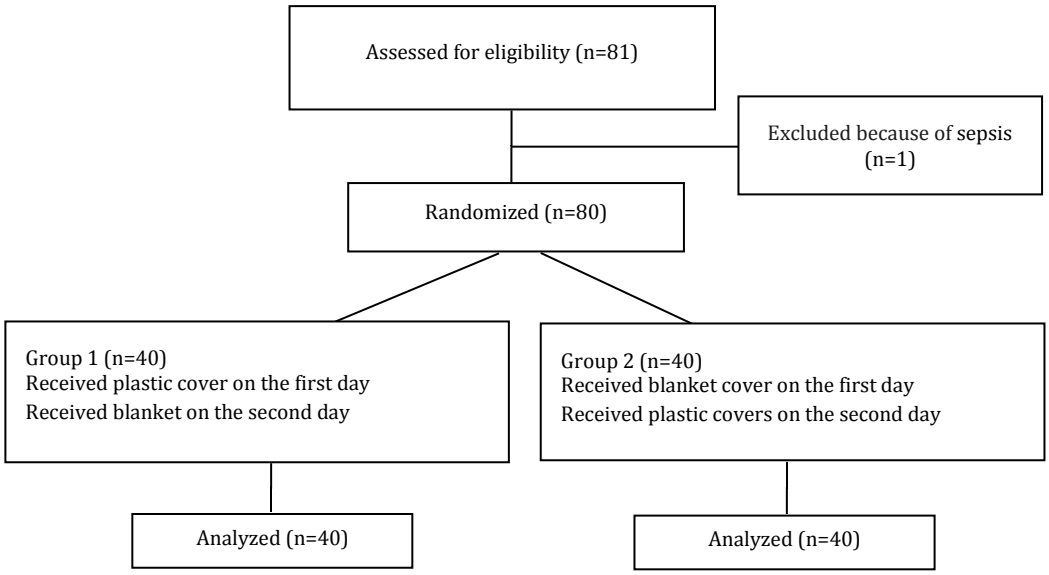

Figure 1. Flow chart of the study

the nipple line).

To ensure that all the infants were under identical conditions, "My Baby" diaper numbers 1, as well as warm and moist oxygen were used. All the blankets, plastic covers, sheets, and the nest were all the same size and identical to each other, and they were all heated prior to being used. The plastic used in this study was the product of Tabriz Derakhshan Plast Co. and was cut into 37×41 pieces. The sheets were made of cotton and the blankets were made of plush with a little fleece, which were the product of Tehran Baleran Plush Co.

During the study period (second and third days of the infants' life), kangaroo mother care was not allowed due to the infants' condition. No other heating or cooling devices were used in NICU, nor was there any airflow. The windows of the unit were double-pane and closed to the ceiling and were covered with a fabric curtain, which was always closed (without sound or light penetrating inside).

After importing the data into a computer, the preterm infants' body temperature, heart rate, and O_2 saturation in both groups were compared at different time points during the study period (-1, 0, 3, 6, 9, 12), the data was analyzed using descriptive (mean and SE, 95%CI) and inferential statistics (repeated measurement and ANCOVA tests) in SPSS, version 13. The flowchart of the study is presented in Figure 1.

Results

Out of all the 80 infants who met the inclusion criteria, 40 infants were randomly allocated to each group. There were no significant differences in infants' demographic characteristics, including gestational age, birth weight, gender, oxygen therapy method, environmental temperature, and moisture, between the groups. In group 1, 53.8% of the infants were boys and the mean age was 29.48±0.08 weeks of gestation. The mean weight was 1117±11.51 g. In group 2, 57.1% of the infants were girls and the means of age and weight were 29.3±0.09 weeks and 1108±13.34 g, respectively.

As Table 1 presents, the mean body temperatures for the infants were measured to be 36.8±0.31˚C and 36.6±0.31˚C for the plastic cover and the blanket groups, respectively. This result showed that infants' body temperature was significantly higher when using plastic cover rather than blanket (P<0.001).

The mean heart rates in groups 1 and 2 were 136.68±0.31 bpm and 136.48±0.31 bpm, respectively. The results indicated no significant differences in terms of heart rate (P=0.991) between the infants in the two groups. Only one case of tachycardia (heart rate=194) was reported when plastic covers were being used.

Means of infants' arterial blood saturation in groups 1 and 2 were 95.19±0.31% and 94.82±0.31%, respectively, which clearly showed that infants required less receptive oxygen when

plastic covers were being used and it resulted in

Table 1. Mean and standard error of measurement of body temperature, heart rate, and O_2 saturation in both groups distinctively based on measuring time and its comparison between the groups (N=80)

Specifications				Times of study						
				8:00 am	9:00 am	12:00 pm	3:00 pm	6:00 pm	9:00 pm	Total
Signs	Group	N§	Day cover	Mean±SE	Mean±SE	Mean±SE	Mean±SE	Mean±SE	Mean±SE	Mean±SE
Body temperature[ℵ] (℃)	1	40	First plastic[€]	36.69±0.02	36.72±0.01	36.82±0.02	36.86±0.02	36.87±0.02	36.9±0.02	36.81±0.31
			Second blanket[¥]	36.85±0.02	36.78±0.02	36.67±0.02	36.65±0.02	36.65±0.02	36.63±0.02	36.7±0.31
	2	40	First blanket	36.73±0.02	36.73±0.02	36.66±0.02	36.6±0.03	36.62±0.02	36.66±0.01	36.67±0.31
			Second plastic	36.66±0.02	36.71±0.01	36.82±0.02	36.88±0.02	36.93±0.02	36.94±0.02	36.82±0.31
			P-value model	Matching=0.183 Treatment<0.001 Day<0.001 Time<0.001						
			P-value confounding	O_2 therapy < 0.001						
Heart rate (per minute)	1	40	First plastic	136.53±2.09	136.48±2.03	138.55±1.73	136.1±1.67	138±1.5	139.95±1.64	137.6±0.31
			Second blanket	135.6±1.61	136.73±1.75	135.25±1.99	133.85±2.07	135.7±1.8	137.45±1.94	135.76±0.31
	2	40	First blanket	137.3±1.96	136.83±1.65	133.5±1.87	129.53±1.49	132.3±1.45	136±1.69	134.24±0.31
			Second plastic	134.8±1.8	137±1.77	138.68±1.76	139.18±1.68	141.1±1.65	141.58±1.75	138.72±0.31
			P-value model	Matching=0.787 Treatment=0.991 Day<0.001 Time=0.030						
			P-value confounding	Age=0.031 O_2 therapy<0.001						
O_2 saturation(%)	1	40	First plastic	94.45±0.26	95.13±0.28	95.9±0.28	95.4±0.26	95.45±0.25	95.58±0.23	95.32±0.31
			Second blanket	95.38±0.36	95.13±0.38	95.2±0.28	94.45±0.3	94.88±0.35	95.4±0.31	95.07±0.31
	2	40	First blanket	93.88±0.36	95.5±0.31	94.85±0.42	94.93±0.4	94.33±0.37	95.05±0.35	94.75±0.31
			Second plastic	94.13±0.3	94.85±0.31	94.5±0.31	95.08±0.29	95.25±0.32	95.6±0.29	94.9±0.31
			P-value model	Matching=0.200 Treatment=0.015 Day=0.040 Time<0.001						
			P-value confounding	Age=0.018 Preterm=0.034 Twin<0.001						

§N: The number of infants in each group

ℵ Body temperature: Infants' axillary temperature was measured by digital thermometer.

€Plastic: In group 1, firstly plastic covers were used during one day, and blankets used during the following day.

¥Blanket: In group 2, firstly blankets were used during one day, and plastic covers used during the following day.

reduced amounts of FiO_2 after each measurement (P=0.015).

Discussion

The results of the study indicated that the mean body temperature of the neonates was more constantly within the normal range while using plastic cover compared to blanket, with no incidence of hyperthermia. There were other clinical studies that obtained similar findings. In those studies, the infants in the experimental group were put in plastic bags shortly after birth, while the ones in the control group received the routine care. Smith et al. and Reilly et al. showed that the mean body temperature was higher in the experimental group. The difference in the cases of hyperthermia was not statistically significant between the two groups in those studies (P>0.05) (17, 28).

The studies conducted by Blesches et al., Reilly et al., and Rohana et al. revealed that the mean of infants' body temperature was considerably higher in the group in which polyethylene bags were employed; however, the rate of hypothermia was lower. The difference between studies was probably because of the infants' age range (28-30). In the study by Belsches et al., only one case of hyperthermia was reported (29). Ibrahim and Yoxall also reported a significant reduction in the prevalence of hypothermia (from 25% to 16%) by covering the infants with plastic bags for less than 30 minutes. In that study, unlike the present one, a high percentage of infants suffered from hypothermia, while only one case of hypothermia was observed in the current study. Moreover, the Ibrahim and Yoxall study was of retrospective kind (31).

Fernanda et al. conducted a cohort prospective study and demonstrated that when a plastic bag was used at the time of admission to NICU, the incidence of hypothermia was reduced (32). The results of that study were consistent with those of the current one and it was reported in both studies that use of plastic covers resulted in the regulation of preterm infants' body temperature and prevention of hypothermia.

The differences between the present study and the previous ones were manifold. Firstly, the previous studies were conducted on preterm infants immediately after birth in the delivery unit, surgery room, or 1 hour after NICU admission. However, we carried out the current study on 2-day-old preterm infants hospitalized in NICU. Secondly, in previous studies the infants were placed inside the plastic bags while in the present study the infants were covered with plastic covers up to their neck, just as with blankets. Another difference was in age range and birth weight. The results of studies by Baumgart and Cardona et al. on vital signs of infants were consistent with those of the current study, both indicating no significant differences in heart rate between the group with plastic covers and the other group (33, 34). In line with the present study, Baumgart showed that the infants used less oxygen when they were covered with a plastic

wrap rather than no cover at all. Furthermore, oxygen saturation of arterial blood in infants was higher when plastic cover was used, indicating less need for oxygen consumption (33).

The evaluation of the secondary outcomes of the study also suggested no allergy or skin irritation among the infants when plastic covers were used, which was consistent with the results of other studies (33, 35).

Conclusion

This study was performed on preterm infants of 28-30 weeks of gestation with birth weight of 800-1250 g, who were admitted to NICU. The results of this study showed that body temperature and arterial blood oxygen saturation were higher in the plastic cover group. Considering the infants' heart rate, no statistically significant differences were observed between the groups. Using plastic covers as an inexpensive, applicable, and effective intervention can be beneficial in regulating infants' body temperature and oxygen consumption.

Study limitations

Infants included in the study were kept under radiant heater and were cared for under nasal CPAP or HFNC; therefore, the results might not be generalizable to other preterm infants inside an incubator or cot, or under ventilation. Except for studies mentioned in the discussion section, no other study relevant to the effect of plastic covers or blankets on preterm infants' vital signs was found; therefore, we could not compare this study with further investigations.

Recommendations for practice

The data was collected from 8:00 to 21:00 and the data for other points of time, which could affect the results, were not collected. Therefore, future studies are recommended to collect the data for the entire 24 hours accompanied by respiratory and supportive care.

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Conflicts of interests

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