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Comparison of the Effect of Plastic Cover and Blanket on Body Temperature of Preterm Infants Hospitalized in NICU: Randomized Clinical Trial

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ABSTRACT

Introduction: Preterm infants are unable to regulate their body temperature and there are insufficient research evidences on different kinds of covers for hospitalized preterm infants; therefore, the present study was conducted with the aim of comparing the effects of plastic and blanket covers on the body temperature of preterm infants under radiant warmer.

Methods: This randomized cross-over clinical trial was carried out upon 80 infants with the gestational age of 28-30 weeks and birth weight of 800- 1250 gr who were in Neonatal Intensive Care Unit on the second day of their hospitalization. The study lasted for two days. In group 1, the plastic cover was used during the first day of the study while the blankets were used during the second day. Infants' heads were kept out of the cover and coated with a hat. In group 2, the plastic cover was used during the first day of the study while the blanket was used during second day. Digital thermometer was used to measure infants' axillary temperature. The data was analyzed using SPSS ver 13 and MiniTab software. Descriptive statistics, (Mean (SE), 95%CI) and inferential statistics (Repeated measurement and ANCOVA tests) were used.

Results: The mean body temperature of the infants in the group covered with the plastic was calculated to be higher and the warmer was set on low temperature.

Conclusion: Using plastic cover during the first few days of hospitalization in NICU resulted in regulation of preterm infants' body temperature.

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Introduction

A preterm infant refers to any infant born alive before 37th week from the first day of the last menstrual period (LMP).¹ One of the most important problems of preterm infants is their inability in regulating their body temperature.² The higher ratio of the body surface area to body mass, weak heat insulation due to lack of subcutaneous fat and trans-epidermal water loss are normally included among the reasons for heat loss in preterm infants as well as their inefficiency in controlling their body temperature.³

Heat loss in preterm infants may occur through radiation, evaporation, conduction and convection.⁴ The reduction in the infants'

body temperature is the prime cause of 18-42% of annual infants' mortality rate worldwide.⁵ The increased mortality rate has been reported to be associated with the reduction of body temperature.^{6,7} Infants' hypothermia in NICU increases the probability of their mortality up to 64%(7) while keeping the infants warm leads to 25% mortality reduction in very low birth weight infants.⁸

A preterm infant needs care in the unit called Neonatal Intensive Care Unit (NICU). In NICUs, a lot of personnel participate in taking care of infants. Nurses are the first and the most responsive personnel who recognize infants' potential risks and crucial conditions and take measures to lower those risks.⁹

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Regulating infants' body temperature is one of the nurses' major responsibilities.⁴ and nursing interventions could have an important role in maintaining warm chain, recognizing any problem at the right time and taking prompt treatment steps to prevent relevant side effects.⁹

Hypothermia is known to leave considerable side effects in infants, including a reduction in the surfactant production,³ hypoglycemia, metabolic acidosis, increased oxygen utilization, intraventricular hemorrhage, and a higher level of oxygen dependency.¹⁰

Placing infants under radiant warmer is one of the routine ways of regulating their body temperature and preventing heat loss. However, this way may not be sufficient to prevent heat loss on its own.¹¹ The need to utilize various ways to prevent hypothermia in infants has an essential issue.¹² Covering stops heat transfer and it may happen in two ways: the inner cover which is subcutaneous fat, or the outer layer cover which is created by static air and the clothes.⁹ However, it is quite obvious that infants could have little chance to generate the former type of cover as only 3.5% of infant's body portion is made of fat up to the 30th week of gestation and it is only after 30th week when this portion gradually increases.⁴

The results of the previous studies showed that placing infants inside plastic bags increases their body temperature mean¹³⁻¹⁵ in addition to preventing heat and water loss through skin evaporation.¹⁶ This method could be helpful in maintaining 70- 80% of the moist during the first few days of life.⁹ The rate of hypothermia was considerably lower for these infants and their body temperature mean was comparatively higher in one hour after admission to NICU.^{13,17-20} This method is an easy, inexpensive, practical and efficient way in preventing hypothermia without generating any dermal allergy or requiring an intervention in preterm infant resuscitation.²¹ Studies employing this method reported a reduction of up to 26% in hypothermia.²² A systematic review (Cochrane review) has been

conducted by McCall and his colleagues with the aim of interventions to reduce hypothermia in premature infants.

The results of this study revealed that it is very difficult preterm infants keep warm; even with full compliance with the instructions. Hypothermia is a global problem in all weather conditions, especially for premature infants admitted to neonatal units. The appropriate heat supply using external heat sources might lead to the prevention of encountering these side effects. Keeping a preterm infant warm, even by strictly observing all the instructions is very demanding. Placing the baby under the radiant warmer and the use of plastic bags by virtue of the prevention of waste heat supply and heat of the baby's body temperature. The existing methods of preventing heat loss is necessary but not sufficient. As well as these methods must be improved to be waived because the long-term consequences of their use is not specified. So the researchers recommend that more researches are necessary to be carried out in this area.¹¹ One of the principles of warm chain at the time of birth and neonatal period is infant's bedding (cover, sheet and bed).⁵ Using a blanket under the radiant warmer is a known and traditional way to cover an infant.^{8,23-26} The heat loss can be prevented through radiation and conduction.³

Based on the recommendations in the guidelines, covering an infant with a warm blanket should be done at the time of resuscitation, during skin-to-skin care^{27,28} and after admission to NICU.²²

Although it is a long time since the importance of controlling infants' body temperature was recognized, various ways of regulating preterm infants' body temperature should still be reviewed and interpreted.¹

In Tabriz NICUs, as other centers in Iran, the infants in their first days of admission are placed on the radiant warmer, because of a variety of treatment procedures, easy access to the infants and observation. A plastic tent is put on infants' whole body and the warmer which is hung from sides of the warmer or the

infant is placed inside the plastic bag. The alternative way is to cover the infant with the blanket. Recently, Neonatal Individualized Developmental Care Program (NIDCP) has suggested the use of any cover, up to infants' shoulders, which would make the face obvious and let the eyes watch and see. So, it considers the plastic tent as an obstacle for visual contact between mother and the infant. In view of the fact that plastic cover and the blanket cover have both been used for a long time as economical, easy and safe ways of preventing hypothermia, and yet there have been no studies investigating the possible advantages of one over the other, the present research was initiated with the aim of comparing the effects of these two alternative covers. The goal of the study was to investigate and put to use the most preferred way of regulating infants' body temperature which is based on Neonatal Individualized Developmental Care and Assessment Program (NIDCAP) and does not impede visual contact between mother and the infant.

Materials and methods

This is a single-blind randomized cross-over clinical trial carried out from December 2015 to April 2016 in Taleghani teaching hospital in Tabriz. Having obtained written consent from the parents and permission from the ethics committee with the code number of TBZMED.REC.1394.846 and having registered the study in IRCT website with the code number of IRCT201407218315N11. We enrolled the qualified infants in our study based on admission order in NICU.

Study inclusion criteria were: gestational age of 28-30 weeks, birth weight of 800-1250 grams, being 2-day old, being inborn, being NPO, being hospitalized in NICU from their birth day, being cared under radiant warmer, being under respiratory care in Nasal Continuous Positive Airway Pressure (N-CPAP) or High Flow Nasal Canola (HFNC) way. The infants suffering from spinal cord defects, congenital skin disease, congenital heart disease, omphalocele, gastroschisis, metabolic

diseases, sepsis, being under ventilator and phototherapy were excluded from the study.

With power of 0.8 and 95% confidence, based on the results of similar studies ($SD=0.57$, maximum $\alpha=0.5$)²⁹ and pilot study; using the formula of comparing mean of two population, the sample size in each group was calculated as 35 infants. Considering 10% of attrition, the sample size increased to 40 infants in each group and 80 infants in total. The qualified infants were allocated into two groups randomly. The first case was chosen in the simple random (draw/lottery), with the next cases allocated to each group alternately (ratio1:1). Birth order and hospitalization in NICU determined the number of inclusion in the study. The study period in each group was 2 days. For statistical purposes, measurements took by a single person. For this reason body temperature, skin temperature and warmer temperature in both groups were measured at 8:00, 9:00, 12:00, 15:00, 18:00 and 21:00 O'clock. The principal researcher did interventions and the person handled all measured parameters. The statistical advisor determined how to randomize to intervention and analysis; the statistical consultant was blind and had no information about the advantages and disadvantages of plastic and blankets.

Group 1: The infants were covered with a sheet from 8:00 a.m. to 9:00 a.m. for one hour. (Passing wash out time and removal of the effect of previous cover). At 9:00 a.m. the sheet was removed from the infants' body. From 9:00 a.m. to 8:00 a.m of the next day i.e. for 23 hours, the infants were covered with the plastic cover up to their 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)^{29,30} the infants were covered with the sheet up to their neck (passing wash out time and removal of the effect of previous cover). Afterwards, the same infants' body (except the head) was covered with the blanket for 23 hours. The infants' head was out of the cover and coated with a hat.

In group 2, the procedure was the same as group 1 with the difference of covering infants' body with the blanket during the first 24 hours

and with the plastic cover during second 24 hours. Data collection was done by the researcher herself. The infants' head was out of the cover and was coated with a hat. Infants' axillary temperature was checked by Welch Allyn digital thermometer. Temperatures below 36.5 °C and over 37.5 °C were considered as hypothermia and hyperthermia, respectively.^{30,31} The warmer was on Servo-control mode and skin probe was placed on the infants' skin completely by using hypoallergenic plaster in an open area of the skin (the probe did not put in an area including brown fat such as axillary, liver or skin wrinkles).

The skin probe areas were changed every 3 hours. Warmer's monitor showed the infant's skin and warmer temperature. Skin and warmer temperature were recorded, too. All infants were cared under the similar radiant warmer model HKN-93B. The study instruments were calibrated by the company engineers. To ensure the measured values of temperature were reliable, the correlation between 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, sex, weight, time of birth, gestational age, chronological age, medical diagnosis, etc. Parameters including the body temperature, skin temperature, warmer temperature... were recorded in the table format. Content validity of data collection forms was confirmed by 7 professors of nursing and midwifery faculty and neonatologists from Tabriz University of Medical Sciences.

Before each body temperature control, warmer's heat and environmental heat and moist were checked and the infants were observed for any skin rash, allergies, hyperthermia and skin changes. During temperature measurement, the cover was lowered to the infants' nipple line to make it possible to put thermometer in infants' under warmer (the cover was not lowered below the nipple line).

To ensure that the condition was similar for all infants, "My Baby" diapers number 1 as well as warm and moist oxygen were used. All of the blankets, plastic covers, sheets and the nest were heated in advance and they were all the same size and similar to each other. The plastic used in this study was the product of Tabriz Derakhshan Plast Co, which was cut into 37×41 pieces. The sheets were made of cotton and the blankets were made of plush with little fleece which were the product of Tehran Baleran plush Co. During the study period (second and third day of life) due to the infants' condition, Kangaroo Mother Care (KMC) was not allowed to be done. No other heating or cooling devices were used in NICU and there was no air flow. The windows of the unit were double pane and close to the ceiling which were covered with a curtain fabric and were always closed (with no sound or light penetrating inside).

The data was analyzed using SPSS and Minitab softwares. After entering data outlier data were removed and exchanged with suitable method. Normality was checked with K-S test and using related transform if it was necessary. The nested repeated measure model with controlling confounding variables was used to compare crossovers formed in six times a day between two groups. Five P-value were estimated, the first P-value is P_{matching} for checking matching between groups before intervention, the second is $P_{\text{Treatment}}$ for comparing groups, the third is P_{Daycover} for showing cross effect in each group, the fourth is P_{Time} for comparing six times a day in each group and the final is $P_{\text{Confounding}}$ for showing confounding effect that removed it from the model. The results were formed in Mean (SE) and 95%CI. The statistical significant level was $P<0.05$.

Results

From all 80 infants qualified to be included in the study, 40 infants were appointed to each group through randomization. Infants' demographic characteristics including gestational age, birth weight, sex, oxygen

therapy method, recognition, environmental temperature and moist had no significant differences across groups. In group 1, 53.8% of infants were boys and the age mean was 29.48 (0.08) weeks of gestation. The weight means was 1117 (11.51) gr. In group 2, 57.1% of the infants were girls and the age and weight means were 29.3 (0.09) weeks and 1108 (13.34) gr, respectively.

Mean of body temperature when using the plastic cover and the blanket was 36.8 (0.31) and 36.6 °C (0.31), respectively. This findings clearly showed that infants' body temperature was higher when plastic cover rather than blanket was being used (P=0.000). (Table1, Figure 1, 2)

According to table 1 and Figure 3, Mean of warmer temperature was 36.33 °C (0.31) when

using plastic cover, while it was 36.46 °C (0.31) when using the blanket. This finding suggested that lower temperature was needed in the warmer when using plastic cover compared to the blanket (P=0.000).

According to figure 3, at 8:00, 9:00, 12:00, 15:00, 18:00 and 21:00 o'clock in both groups, when the infants were covered with the plastic cover, the axillary temperatures were increasing gradually and there was little need for the heat of the radiant warmer. However, this phenomenon was the opposite when using the blanket.

According to table 1 and figure 1, Mean of skin temperature was 36.21°C (0.31) when using plastic cover, while it was 36.21°C (0.31) when using the blanket. The results indicate that there was no significant difference in

Table 1. Mean and Standard Error (SE) of the Skin temperature, Body temperature and Warmer temperature in both groups distinctively based on measuring times and its comparison across groups. (Each groups=40) ¥

Specifications		Times of Study						
Group [‡]	Day Cover	8:00 AM Mean (SE)	9:00 AM Mean (SE)	12:00 PM Mean (SE)	3:00PM Mean (SE)	6:00 PM Mean (SE)	9:00 PM Mean (SE)	Total Mean (SE)
Skin[‡] Temperature								
1	First Plastic	36.16 (0.02)	36.19 (0.01)	36.27 (0.02)	36.31 (0.02)	36.32 (0.02)	36.32 (0.02)	36.26 (0.31)
	Second Blanket	36.21 (0.01)	36.2 (0.01)	36.15 (0.02)	36.15(0.02)	36.15 (0.02)	36.15 (0.02)	36.17 (0.31)
2	First Blanket	36.17 (0.02)	36.19 (0.01)	36.15 (0.02)	36.13(0.02)	36.11 (0.02)	36.16 (0.01)	36.15 (0.31)
	Second Plastic	36.13 (0.01)	36.16 (0.02)	36.26 (0.02)	36.33(0.02)	36.37 (0.02)	36.35 (0.02)	36.27(0.31)
P [§]	Model	Matching = 0.836		Treatment =0.284		Day =0.000	Time =0.000	
	Confounding	Age = 0.018	Preterm = 0.034	Twin =0.001				
Body[§] Temperature								
1	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	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	Model	Matching = 0.183		Treatment =0.000*		Day =0.000	Time =0.000	
	Confounding	O2 Thrapy = 0.000						
Warmer Temperature								
1	First Plastic	36.4(0.03)	36.4(0.03)	36.4(0.03)	36.31(0.03)	36.24(0.03)	36.23(0.03)	36.33(0.31)
	Second Blanket	36.28(0.03)	36.33(0.03)	36.4(0.03)	36.47(0.03)	36.52(0.03)	36.52(0.03)	36.42(0.31)
2	First Blanket	36.41(0.02)	36.42(0.02)	36.42(0.02)	36.48(0.03)	36.52(0.03)	36.55(0.03)	36.46(0.31)
	Second Plastic	36.46(0.02)	36.46(0.02)	36.43(0.02)	36.33(0.03)	36.21(0.03)	36.16(0.03)	36.34(0.31)
P	Model	Matching = 0.717		Treatment =0.000*		Day=0.000	Time =0.067	
	Confounding	Age = 0.002	Tachypnea =0.000					

[‡]Skin temperature (°C): Infants' skin temperature measured with warmer probe. [§]Body temperature (°C): Infants' axillary temperature measured by digital thermometer. [‡]In group 1, during first day, the plastic cover and during second day the blanket was used. In group 2, during first day, the blanket and during second day the plastic cover was used. [§]Sample size in each group. [¶]ANCOVA nested repeated measurement tests (with controlling confounding variables) was used. [¥]The statistical significant level is P<0.05.

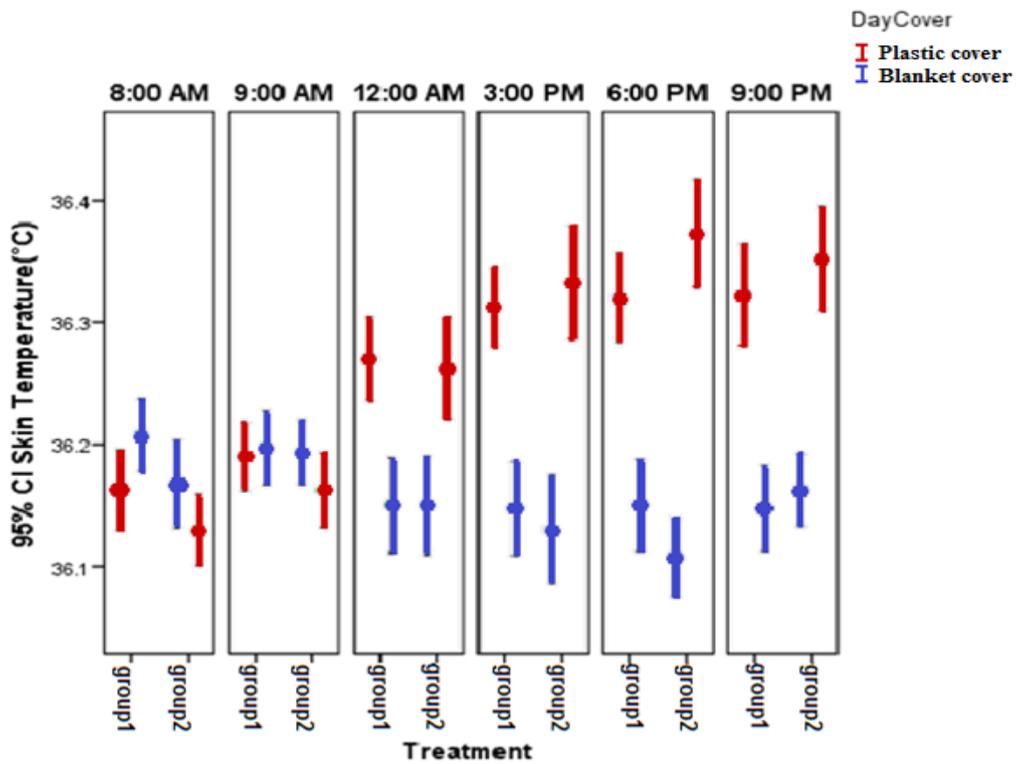


Figure 1. The rate of skin temperature in both groups at the measurement times and comparing it across groups.

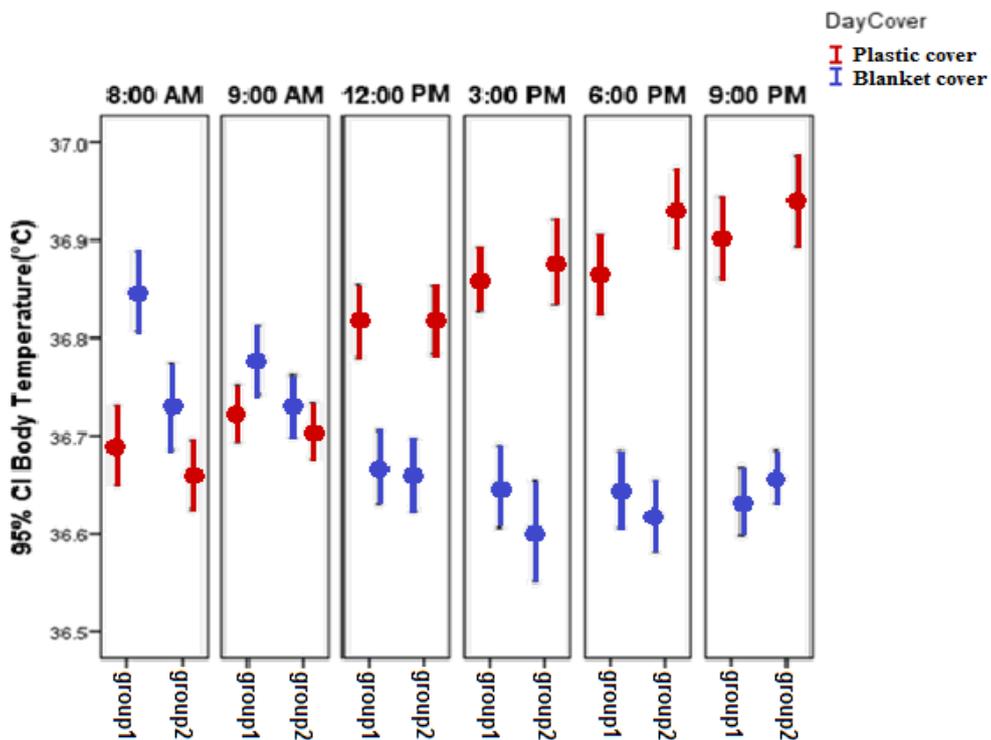


Figure 2. The rate of body temperature in both groups at the measurement times and its comparison across groups

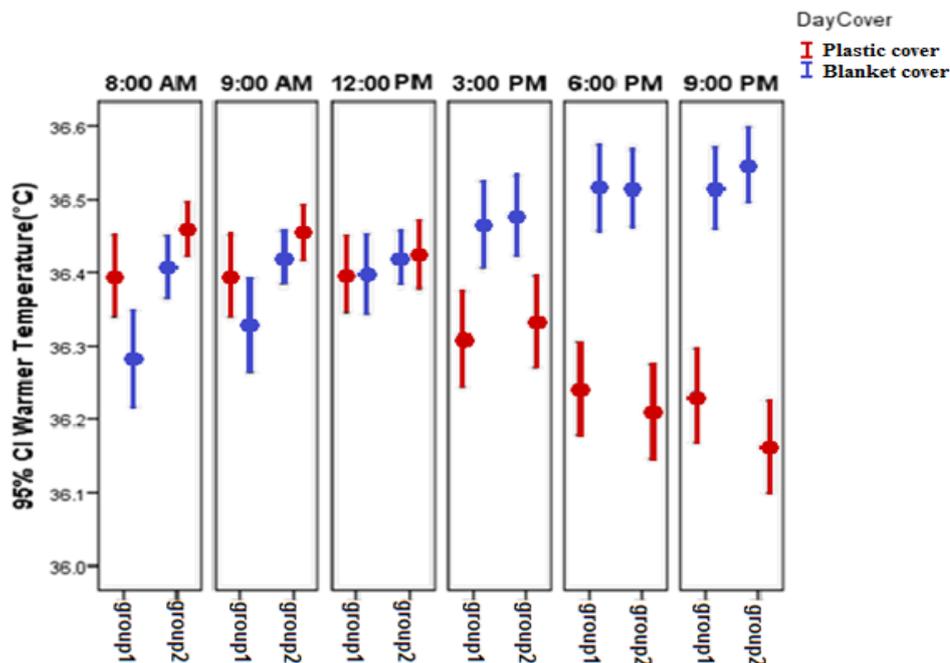


Figure 3. The rate of Warmer temperature in both groups at the measurement times and comparing it across groups

terms of skin temperature when plastic cover or blanket cover were used for infants in the two groups (P=0.284). According to Table 2, when the blanket was used, 14 cases of hypothermia were observed in both groups.

However, no cases of hypothermia was reported when the plastic cover was used and there was only a single case of hyperthermia (T=37.9°C). Statistically, no differences was observed in the temperature infants' skin (P=0.28) in either group.

Table 2. Distribution of Body temperature in both groups, by the time of measurement and comparison between groups (N = 80)

Group	Day Cover	Body Temperature (°C)	Times of Study					
			8:00 AM	9:00 AM	12:00 PM	3:00 PM	6:00 PM	9:00 PM
1	First plastic	Normal	40	40	40	40	40	40
	Second blanket	Hypothermia	0	0	2	2	1	0
2	First blanket	Normal	40	40	38	38	39	40
		Hypothermia	0	0	2	5	2	0
	Second plastic	Normal	40	40	38	35	38	40
		Hyperthermia	40	40	40	40	39	40
		Hyperthermia	0	0	0	0	1	0

Discussion

The results of this study clearly showed that the body temperature of 28-30 weeks gestation infants hospitalized in NICU, for whom plastic cover was used, was within normal limits compared to those for whom

the plush blanket was used. Plastic cover group used less warm heat.

Placing the infant inside the plastic bag has been mentioned in clinical trials and various Meta analyses.^{13,17-20} Smith et al., has come up with the same results as those of

the current study. The mean of body temperature at the time of admission to NICU was 36.26°C in the intervention group and 35.79°C in the control group and this difference was statistically significant ($P=0.001$). Smith *et al.*, used plastic bags for newborns at the moment of birth and before admission hospitalization in NICU.¹⁵

The results of Kent and Williams study also showed that infants' body temperature increased by using polyethylene cover. Environmental temperature had been increased as well in the operating theatre.³¹

Cardona *et al.*, showed that the temperature of 36.5°C was achieved 30 minutes after birth in the group in which infants were placed inside the plastic bags while, in groups in which plastic bags were not used, the same temperature was achieved after 75 minutes. Newborns with gestational age of 28-30 weeks and birth weight of 1000 to 2499 gr were included in Cardona *et al.*, study.¹³

Vohra *et al.*, showed that mean of body temperature in newborns after delivery and at admission time to NICU were higher in a group in which the plastic bag was used compared to the control group. Their study had been conducted upon preterm infants with gestational age of lower than 28 weeks.³²

Baumgart's study showed that when an infant was covered with a wrap made of plastic rather than no cover at all, the warmer temperature was lower. Skin temperature violations were not significant, either.³³

The differences between the present study and other studies were related to using plastic cover and plush blanket, infants' age range and the study settings. We carried out this study in preterm infants during the second and third days of hospitalization in NICU and considered their age range and birth weight and used plastic cover up to their neck like a blanket while keeping their head out of the cover. This was the routine method in using the plush blanket. However, in the previous

studies, infants were placed inside the plastic bags and only their head was out of the bag and the study was done in preterm infants immediately after birth in the delivery ward and surgery rooms up to 1 hour after admission to NICU.

As for the limitations of the study, it has to be mentioned that the collected data, which was analyzed, was for 13 hours from 8:00 am to 21:00 pm to ensure closer and more accurate observation and recording. The data for other times were not collected.

Conclusion

The results of this study showed that using plastic cover was effective in regulating the body temperature of preterm infants of 28-30 weeks gestation and birth weight of 800-1250 gr who were in NICU on the 2nd and 3rd days of their hospitalization. Plastic cover is an inexpensive, effective and simple device to use for causes with no allergy or skin irritations. However, this method had no effect on the infants' skin temperature and no difference was observed across groups. The results of this study showed that body temperature was higher and there was less warmer heat consumption while using plastic cover.

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Ethical issues

None to be declared.

Conflict of interest

The authors declare no conflict of interest in this study.

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