Effect of Polyethylene Bag to Prevent Heat Loss in Preterm Infants at Birth: A Randomized Controlled Trial

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Background: *Hypothermia at birth has been associated with increased morbidity and mortality in preterm infants.*
Objective: *To evaluate the effect of wrap with polyethylene bag at birth on admission temperatures and the incidences of hypothermia on admission in preterm infants gestational age ≤ 32 weeks.*
Material and Method: *A randomized controlled trial was conducted in thirty-eight preterm infants with gestational age ≤ 32 weeks. The infants were assigned and placed in polyethylene bag immediately after birth without drying under a radiant warmer or received standard thermal care including being dried and placed under a radiant warmer. Rectal temperatures were recorded on admission to neonatal unit and incidences of hypothermia were compared between the two groups.*
Results: *The body temperatures of preterm infants with polyethylene bag were significantly higher than those of the control group {median 36.5°C (range 35.5°C-37.2°C) vs. 35.9°C (range 34.9°C-36.5°C), p < 0.001}. On admission, the incidence of hypothermia in preterm infants wrap with polyethylene bag was significantly lower than in the control group (26% vs. 89%, p < 0.001) with a risk reduction of 0.63 (95% CI 0.39-0.87) and a number needed to treat of 1.58.*
Conclusion: *Polyethylene bag prevents heat loss at delivery in preterm infant less than 32 weeks gestation. Incidence of hypothermia was significantly reduced by use of polyethylene bag, a simple and inexpensive intervention.*

Keywords: *Hypothermia, Preterm infants*

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Hypothermia at birth has been associated with increased morbidity and mortality in preterm infants[1-3]. Although, preventing low body temperature at birth in preterm infants is important to survival and long term outcomes. Keeping preterm infants warm immediately after birth, especially during resuscitation, is problematic even when routine thermal care guidelines are followed. Many preterm infants have been hypothermic on admission in neonatal intensive care unit (NICU), despite adherence to Neonatal Resuscitation Program (NRP) recommendations for the thermal management of preterm infants during resuscitation[4] and others attempts to minimize heat loss. In Thammasat University, the incidence of hypothermia in preterm infants birth weight less than 1,500 gm was 80% in which 30% had rectal temperature lower than 35.5°C. Similarly, the incidence of hypothermia at birth between 42% and 73% has been reported[5-7].

The American Academy of Pediatrics and American Heart Association's Neonatal Resuscitation Program (NRP) recommended a reclosable polyethylene bag to prevent hypothermia if the baby is born at less than 28 weeks gestation[8]. Recent studies have demonstrated the effectiveness of occlusive polyethylene wrap to improve admission temperature and reduce evaporative heat losses in preterm infants when used during the immediate resuscitation period[9-11].

The present study aimed to determine the effectiveness of placing infants less than 32 weeks gestation or birth weight below 1,500 gm in polyethylene bag in the delivery room.

Material and Method

A randomized controlled trial was studied to compare the effect of polyethylene bag with standard thermal care at Thammasat Hospital from 1 March 2010 to 31 January 2011. Parental consent was sought if the mother was expected to deliver before completing 32

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weeks gestation. Enrolled infants were randomly assigned to control or polyethylene bag group. The infants were stratified by gestational age (< 28 weeks or ≥ 28 weeks). A block of 4 randomizations was used to ensure a balance of infants in each allocation. Randomization was carried out in the delivery room by opening (opaque-sealed) envelops just prior to birth. Exclusion criteria included congenital anomalies with open lesions (*e.g.* gastroschisis, meningomyelocele), imperforated anus and polyethylene bag being cut because of emergency umbilical vein catheterization. Hypothermia was defined as a rectal temperature less than 36.5°C.

All infants were stabilized in the delivery room under radiant warmers. The control infants were routinely dried under radiant warmer, followed by propered airway management and observation of vital signs according to the International Guidelines for Neonatal Resuscitation[4]. For polyethylene bag group, a polyethylene bag was opened under the radiant warmer, and the infant was placed into it from the shoulders down (Fig. 1). The body was wrapped without drying except for the head and then airway was managed and vital signs were assessed through the transparent polyethylene bag. The bag size was 27 x 28 cm. After initial stabilization, control infants covered with polyvinyl wrap as a standard thermal care in our hospital. All infants in both groups were covered with warm blankets and transferred to the neonatal unit with prewarm transport incubators.

Upon arrival at NICU, the infants were placed under radiant warmers and the polyethylene bags were removed. Rectal temperatures were taken immediately with a digital rectal thermometer. All infants received standard protocol of neonatal care.

Fig. 1 Infant placed in polyethylene bag

The primary outcomes include the incidence of hypothermia and a median temperature on admission.

Secondary outcomes include mortality rate, duration of hospitalized, first serum glucose concentration and possible adverse effects associated with using polyethylene bag including hyperthermia, skin maceration and interference with resuscitation.

The maternal temperatures, delivery room temperatures, transport incubator temperatures, nursery temperatures and time of admission to the neonatal unit were recorded.

The present study has approved the ethical consideration by the ethical committee, Thammasat University: Code MTU-P-1-82/52.

Sample size estimation

Power analysis indicated that 19 infants in each group would provide 90% power to detect a postulated 50% reduction (from 0.76 in control group to 0.26 in polyethylene bag group) in the incidence of hypothermia using a 0.05 level test of significance.

Statistical analysis

Analysis was conducted using SPSS v13. Comparing categorical data between the two groups were analyzed using the Chi-square test or Fischer's exact test when appropriate. Comparing continuous data between the two groups were analyzed using Mann-Whitney U-test. A p-value less than 0.05 were considered significant.

Results

Thirty-eight infants were enrolled, 19 in the polyethylene bag group and 19 in the control group. Demographic characteristics were not significantly different between the polyethylene bag and the control group (Table 1).

The environmental temperatures were similar in both groups (Table 2).

The median rectal temperature on admission to the neonatal unit in the polyethylene bag group (36.5°C range 35.5°C-37.2°C) was 0.6°C higher than that in the control group (35.9°C range 34.9°C-36.5°C), $p < 0.001$. The incidence of hypothermia on admission to the neonatal unit was significantly lower in the infants wrap with polyethylene bag than that in the control infants (26% vs. 89%, $p < 0.001$), with a risk reduction of 0.63 (95% CI 0.39-0.87) and a number needed to treat of 1.58 (Table 3).

The majority of infants in polyethylene bag group had higher admission temperatures than

Table 1. Baseline characteristics of infants and mothers between the two groups

Characteristics	Polyethylene bag group n = 19	Control group n = 19	p-value
Mothers			
Antenatal steroids, n (%)	14 (73)	15 (78)	1.000
Duration of membrane rupture(hr), median (range)	2.3 (0.08-50)	2.3 (0.22-15)	0.796
Infants			
Birth weight (g), median (range)	1,300 (685-1,570)	1,230 (675-1,615)	0.274
Gestational age (wk), median (range)	29 (25-33)	29 (24-32)	0.894
Female sex, n (%)	12 (63)	7 (36)	0.194
Multiple births, n (%)	4 (21)	9 (47)	0.170
Route of delivery			
Normal, n (%)	8 (42)	3 (16)	
Cesarean section, n (%)	11 (58)	16 (84)	0.151
APGAR score, median (range)			
At 1 min	9 (1-9)	7 (1-9)	0.104
At 5 min	10 (1-10)	10 (2-10)	0.078
Time of admission to the neonatal unit (min), median (range)	15 (5-25)	15 (7-40)	0.204

Table 2. Environmental Temperatures between the two groups

Environmental temperatures	Polyethylene bag group median (range)	Control group median (range)	p-value
Maternal temperatures (°C)	37.0 (36.8-37.3)	37.0 (36.8-37.4)	0.707
Delivery room temperatures (°C)	25.0 (25.0-26.0)	25.0 (25.0-26.0)	0.808
Transport incubator temperatures (°C)	37.0 (35.5-37.0)	37.0 (35.5-37.0)	0.324
Nursery temperatures (°C)	26.0 (25.0-26.0)	26.0 (25.0-26.0)	0.561

Table 3. Admission temperatures and incidence of hypothermia between the two groups

	Polyethylene bag group (n = 19)	Control group (n = 19)	p-value
Admission Temperatures (°C)			
median	36.5	35.9	< 0.001
range	35.5-37.2	34.9-36.5	
Hypothermia, n (%)	5 (26)	17 (89)	< 0.001

infants in the control group. All five infants birth weight < 1,000 gram had hypothermia at NICU admission. Infants in the polyethylene bag group had higher admission temperatures (range 35.5°C-36.5°C) than those in the control group (range 34.9°C-35.0°C) (Fig. 2).

Mortality, duration of hospitalization, first means blood glucose level were not significantly different between the two groups in the secondary outcomes measured (Table 4), rectal temperature at NICU admission had been $\leq$ 35.5°C in 1 of 2 deaths in the polyethylene bag group, compared with 2 of 2 deaths in the control group.

Adverse events including hyperthermia, skin maceration and infection such as omphalitis were not identifying in both groups. The use of polyethylene bag was well accepted by the neonatal staff and did not interfere with resuscitation in the delivery room.

Table 4. Clinical Outcomes between the two groups

	Polyethylene bag group (n = 19)	Control group (n = 19)	p-value
Death before discharge, n (%)	1 (5)	2 (10)	0.487
Hospital stay (days), median (range)	39.5 (4-101)	45 (1-111)	0.256
Blood sugar on admission (mg/dL),median (range)	80 (39-139)	76 (41-183)	0.953

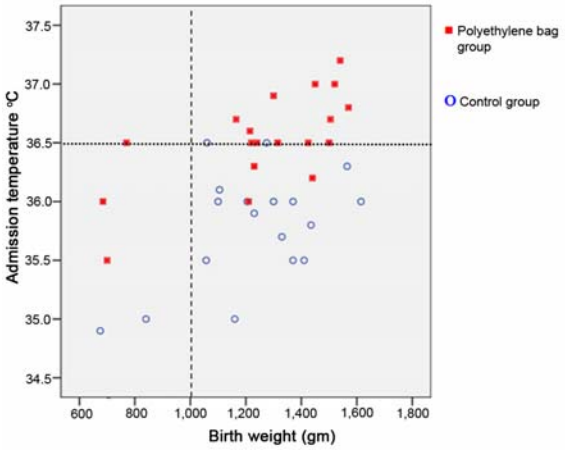

Fig. 2 Relation between birth weight and admission temperature of infants in the polyethylene bag group and the control group

Discussion

The present study reported the lower incidence of hypothermia on admission by the use of an occlusive polyethylene bag in preterm infants less than 32 weeks gestation immediately after birth and during resuscitation than conventional method.

Preterm infants are highly vulnerable to develop cold stress particularly in infants birth weight <1,500 gram. These infants have a diminished capacity for metabolic heat production coupled with a high surface area to body weight ratio and an immature epidermal barrier, leading to high evaporative heat loss. The significance of evaporative heat loss in newborn infants has been recognized[12]. Preterm infants are known to increase insensible water loss[13]. The primary mechanism of action of the occlusive covering is probably reduction of evaporative heat loss, but there may also be an effect on convection heat loss. The thin layer between infant's skin and bag, after entrapped by the occlusive barrier and warmed by the infant via conduction, may provide as insulation. Convection heat losses are also reduced by covering the infant. Wrapping with polyethylene bag is a simple, noninvasive and inexpensive intervention. The intervention is easy to implement for thermal management for preterm infants during resuscitation.

The environmental temperatures constantly have effect on admission temperatures. In the present study, the temperature in delivery room was kept at 26°C for every preterm delivery. The environmental temperatures related to thermal control were similar in both groups.

The risk of overheating is a potential concern when using the polyethylene bag[14]. In the present study, overheating was not identified in the authors infants placed into the polyethylene bag.

Hypothermia immediately after birth in extremely preterm infants was associated with a reduced change of survival in the EPICure study[1]. In the present study mortality rate was not difference between groups. Larger controlled studies are needed to determine whether or not reduction of early hypothermia results in improved survival or other long-term benefits.

The effectiveness of polyethylene bag at birth to prevent hypothermia in preterm less than 28 weeks has been shown in recent randomized control trials[5,6,9]. In the present study the benefit in infants below 28 weeks gestation seem limited. The authors speculated that the instability of temperatures in delivery room and transport incubator might contribute to the authors results.

Conclusion

The present study has demonstrated that polyethylene bag is effective to prevent hypothermia in preterm infants immediately after birth.

Acknowledgement

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Potential conflicts of interest

None.

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ประสิทธิภาพของการใช้ถุงพลาสติกโพลีเอทธีลีนในขณะแรกคลอดในการป้องกันภาวะอุณหภูมิกายต่ำในทารกเกิดก่อนกำหนดในโรงพยาบาลธรรมศาสตร์เฉลิมพระเกียรติ

ทรงเกียรติ ฉันทโรจน์, วิไลพร เตชะสาธิต

วัตถุประสงค์*: เพื่อเปรียบเทียบประสิทธิภาพในการลดการเกิดภาวะอุณหภูมิกายต่ำระหว่างการใช้ถุงพลาสติกโพลีเอทธีลีนในขณะแรกคลอดกับกลุ่มควบคุม ในทารกเกิดก่อนกำหนดอายุครรภ์น้อยกว่าหรือเท่ากับ 32 สัปดาห์ ในโรงพยาบาลธรรมศาสตร์เฉลิมพระเกียรติ*

วัสดุและวิธีการ*: การศึกษารูปแบบ prospective randomized controlled trial ทารกเกิดก่อนกำหนดอายุครรภ์น้อยกว่า หรือเท่ากับ 32 สัปดาห์จะถูกสุ่มเป็น 2 กลุ่ม กลุ่มละ 19 คน ทารกกลุ่มควบคุมได้รับการป้องกันการสูญเสียความร้อน ด้วยการวางทารกใว้ใต้เครื่องแผ่รังสีความร้อนและเช็ดตัว ในขณะที่ทารกกลุ่ม polyethylene bag จะได้รับการวางทารกใว้ใต้เครื่องแผ่รังสีความร้อน และสวมถุงพลาสติกโพลีเอทธีลีนทันทีหลังเกิดโดยไม่ได้รับการเช็ดตัว จากนั้นจะติดตามอุณหภูมิกายแรกรับที่หอผู้ป่วย และอัตราการเกิดภาวะอุณหภูมิกายต่ำเมื่อแรกรับที่หอผู้ป่วย*

ผลการศึกษา*: ค่า median ของอุณหภูมิกายแรกรับที่หอผู้ป่วยในทารกกลุ่มที่ได้รับการสวมถุงพลาสติกโพลีเอทธีลีนสูงกว่ากลุ่มควบคุม 0.6°C (36.5°C และ 35.9°C ตามลำดับ p < 0.001) และพบภาวะอุณหภูมิกายต่ำเมื่อแรกรับที่หอผู้ป่วยในกลุ่มที่ได้รับการสวมถุงพลาสติกโพลีเอทธีลีนน้อยกว่ากลุ่มควบคุมอย่างมีนัยสำคัญทางสถิติ (ร้อยละ 26 และ ร้อยละ 89 ตามลำดับ p < 0.001) โดยมีค่า risk reduction เท่ากับ 0.63 และมี number need to treat เท่ากับ 1.58*

สรุป*: การใช้ถุงพลาสติกโพลีเอทธีลีนในขณะแรกคลอดสามารถป้องกันการสูญเสียความร้อนได้ดีในทารกเกิดก่อนกำหนดอายุครรภ์น้อยกว่า 32 สัปดาห์ เป็นวัสดุที่หาได้ง่าย ราคาไม่แพง และมีความปลอดภัยที่จะนำมาใช้กับทารก*