Original article:

Safety and efficacy of vinyl polyurethane bags in prevention of hypothermia in very low birth weight preterm neonates at birth in delivery room

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ABSTRACT

Title: Safety and efficacy of vinyl/polyurethane bags in prevention of hypothermia in very low birth weight preterm neonates at birth in delivery room

Objectives: Preterm infants are prone to hypothermia immediately following birth. Among other factors, excessive evaporative heat loss seems to be an important contributor. We compared the effect of standard care vs the use of vinyl bags (Vi Drape)/polyurethane on admission temperature in extremely preterm infant's <31weeks gestational age born vaginally or by caesarean section.

Methods: Forty premature infants with similar baseline characteristics were assigned and placed in vinyl/polyurethane bags (n=20) immediately following delivery without drying or received standard care (controls n=20) including drying and placement under a radiant warmer . Axillary temperature was recorded on admission to neonatal unit.

Results: The average temperature in the vinyl bag group was significantly higher (35.83±0.48 vs 35.16±0.60,p value-0.0004) and also the axillary temperature was significantly higher in study group compare to control group (36.58 ±0.72 vs 35.79± 0.48, p value-0.003). In the secondary outcome there was no difference in mortality, fluid requirement, PDA, IVH & Surfactant need between two groups.

Conclusion Vinyl bags/polyurethane bags prevent heat loss and are a simple and effective intervention in preventing hypothermia in the delivery room .

Key words: premature, vinyl/polyurethane bags, hypothermia

Introduction:

Adaptations to extrauterine life involves the newborn infant in a series of biologic adjustments to a totally new set of environmental conditions. Prime among these is the accommodation to a thermal environment that, in all but the most tropical countries, represents a distinctly "cold" challenge. The failure to accommodate to this cold stress has historically been recognized as perhaps the earliest different characteristic (other than size) of the premature as opposed to the term neonate.

Standard care includes providing a warm delivery room at a minimum of 25°C (although rarely achieved in practice),drying the infant thoroughly, immediately after birth (especially the head) , removing any wet blankets, wrapping in a pre warmed blanket, pre warming any contact surfaces, eliminating draughts and close proximity to outside

walls. If available, radiant warmers for resuscitation and stabilization allow easy access and are effective in preventing heat losses, provided that the infant is immediately dried and placed under the pre warmed heater. Although the infant gains heat by radiation, there are increased potential losses through convection and evaporation and these losses are exacerbated if the infant is inadequately dried.

The introduction of different transparent membranes has made it possible to limit evaporative and convective heat loss and to permit heat gain through radiation. This appears to be a very inexpensive and effective mode of preventing hypothermia in extremely premature infants.

Earlier studies showed that hypothermia is significantly associated with mortality and morbidity and very preterm babies is prone to develop hypothermia in early hour of life. Similarly in our institute we are dealing with very preterm deliveries frequently. Therefore, the present study was planned to evaluate the safety and efficacy of vinyl/polyurethane bags in prevention of hypothermia compared to sterile PVC sheet during resuscitation at birth in very low birth weight preterm neonates.

Material and Methods

This study was conducted in level III tertiary neonatal intensive care unit with 50 beds and 15 ventilators. It is a prospective randomized interventional study over a period of 17months. Blinding of researchers to the intervention was not possible in this trial. This study was approved by the ethical committee of the institute. Very low birth weight infants <31 weeks gestational age who were resuscitated in vinyl bags (Vi-Drape isolation bag)/polyurethane bag and delivered (either vaginally or by caesarean section) in-house were compared with those following standard care in the delivery room. Admission temperature, morbidity and mortality were compared between the two groups. All <31 weeks inborn baby who were delivered during study period were included in study. Infants with major congenital malformations, open neural tube defects, abdominal wall defects or blistering skin conditions were excluded.

We used the Phoenix infant warmer system in the delivery room. All preterm deliveries less than 31 weeks gestational age were conducted in the operating rooms/delivery room in the obstetric suite. The temperature of the Operating room/delivery room was maintained between 24-26^{0}C for these deliveries. The radiant warmers are set at maximal heat output in preparation for these deliveries as soon as the delivery room nurse is notified of an impending preterm delivery. The baby was received from the obstetrician in a prewarmed towel and then placed under a radiant warmer at 100% power immediately.

According to randomization number babies were allocated to study (**Fig 1**) or control group (**Fig 2**). Infants were dried immediately and wrapped in sterile green PVC sheet which is commonly used in delivery and operation room by surgeons/obstetricians and head was dried and covered with woollen hat. Newborn resuscitation was done as per NRP guidelines. In study group infants placed in a Vi-Drape bag/polyurethane placement under a radiant warmer as per NRP guidelines. For other interventions (oxygen administration, ventilation, intubation, chest compressions, and medication), all infants were treated according to the international guideline for neonatal resuscitation [1]. The infants resuscitated in the vinyl bags were placed

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in the bag up to the neck immediately following delivery without drying**.** The bag was secured loosely around the neck by the straps. Only the head was dried and covered by a woolen hat. Auscultation was done over the bag and if umbilical access was required/ or to put pulse oximetry probe a hole was cut in the bag to provide access.

Infants were transported to the NICU in a prewarmed Drager transport incubator (**Fig 3**) set at 38°C. Study group infants were transported with bag and control group infants were covered with warm blankets. Following admission to the NICU the infant was immediately transferred without removal of bags in to a prewarmed isolette (phoenix warmer, omni bed or giraffe incubator) adjusted to the neutral thermal environment for the gestational age of the infant. We had removed vinyl/polyurethane bags after 1 hour till initial stabilization and procedures were completed.

Vital signs including axillary temperature were taken on admission to the neonatal unit. Gestational age (GA) was assessed by the last menstrual period and early antenatal scans. Patient characteristics such as GA, birth weight, gender, prenatal care, antenatal steroids, and chorioamnionitis based on the histological examination were ascertained from the maternal and pathology records.

Primary outcome measure was axillary temperature on admission to NICU and again after 1 hour after removing the wrap. Axillary temperature was measured using digital thermometer. Secondary outcomes measured were occurrence of worst ph in first 6 hour of life, hypotension and PDA, requirement of surfactant and duration of ventilator support, oxygen requirement, Hypoglycemia**,** weight loss and fluid requirement in first four days of life, mortality before hospital discharge, presence of major brain injury (sonographic evidence of intraventricular hemorrhage) and duration of NICU stay.

In previous trial of this intervention, the subgroup of 18 infants <28 weeks gestation had pooled SD of 0.9^0C. We considered mean difference of this magnitude to be clinically important. To detect a mean difference of 0.9^0C in core temperature required the enrolment of 20 infants per treatment group, for an α of 0.05 (2 tailed) and 80% power, we planned to recruit at least 20 infants in each group.

Random numbers were generated from software and sealed envelopes were placed in the OR/DR and fellows attending delivery had opened the envelope and did accordingly.

The two groups were compared using an unpaired t test for continuous variables and Fisher's exact test for non-continuous variables. Statistical analysis was performed using Stat view 4.0 software. A P value of <0.05 was considered to be significant.

Results

Total 40 infants were inducted in the study, 20 infants in each Study group and control group during study period of 17 months. There were no statistical difference in the baseline characteristics such as gestational age, birth weight, antenatal care, antenatal steroids, histological chorioamnionitis, mode of delivery, cord ph, delivery room temperature, APGAR score at 1 and 5 min and transfer time to NICU between the vinyl bags/polyurethane bags and control groups.

(**Table 1**)

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Table 1:Baseline characteristics

	Study group(n=20)	Control group(n=20)	P value
G.A	28.3±1.98	28.2±1.76	0.9(NS)
Birth weight	1030±250	900±263	0.11(NS)
Male(%)	10(50%)	7(36%)	0.52(NS)
Antenatal care (%)	20(100%)	20(100%)	-
Histological chorioamnionitis (%)	Nil	Nil	-
Antenatal steroids (%)	19(96%)	17(86%)	0.6(NS)
Multiple birth	8(40%)	10(50%)	0.75(NS)
Mode of delivery(vaginal/LSCS)	6/14	4/14	0.716(NS)
Cord ph	7.35±0.1	7.3±0.12	0.11(NS)
Delivery room temp(degree centigrade)	25.9±0.64	25.95±1.1	0.168(NS)
APGAR score			
At 1 min	7±0.67	6. ±81	0.65(NS)
At 5 min	8±0.67	7.9±0.95	0.81(NS)

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Table 2

	Study group(n=20)	Control group(n=20)	P value
Transfer time to NICU(In min)	20.7±8.7	25.75±7.3	0.21(NS)
Admission temp in degree ^{o}c	35.83±0.48	35.16±0.60	0.0001
Temp in degree ^{0}c after 1 hr	36.58±0.72	35.79±0.48	0.0003
Hypothermia (%)	0	6(30%)	0.02
Worst ph in first 6 hr of life	7.29±0.1	7.293±0.12	0.99(NS)
BE(mEq/l)	-2.5±3.7	-4.9±3.1	0.03
Maximum oxygen requirement in %	51±21%	45±25%	0.44(NS)
Duration of oxygen requirement in days	9.9±11.3	16.8±20.1	0.18(NS)
Hypotension (%)	10(50%)	12(60%)	0.75(NS)
IVH grade 2-4(%)	1(6%)	4(20%)	0.34(NS)
Death in 30 days	2(10%)	4(20%)	0.66(NS)
PDA (%)	9(45%)	8(40%)	1(NS)
Hypoglycaemia (mg %)	71±11	68±13	0.52(NS)
Duration of intubation required in days	3.8±4.66	6.4±12	0.342(NS)
Duration of CPAP required in days	5.6±11	3.5±4.7	0.43(NS)
No. baby required surfactant	14(70%)	10(50%)	1(NS)
Weight loss in first 3 days of life(grams)	91.25±30.1	88.5±28.3	0.76(NS)
Fluid requirement in first 3 days of life(ml/day)	113±16.2	115.5±22.3	0.68(NS)
Duration of stay in NICU in days	44.45±24.28	40.15±22.7	0.47(NS)

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The mean delivery room temperature and transfer time from delivery to NICU were also similar was similar in both groups. There were no infant in study group that had a temperature over 38^0C in study group. Though the worst ph in first 6 hour were similar in both group, base excess were significantly higher in control group compare to study group (p value-0.03). (**Table 2**)

The average temperature in the study group was significantly higher (35.83±0.48 vs 35.16±0.60).There was difference of 0.7^0C between the average admission temperature in study and control group (p value-0.0004)(**Graph 1**). In study group, polyurethane/vinyl bag were removed one hour later and axillary temperature was taken (**Graph 2**). The axillary temperature was significantly higher in study group compare to control group (36.58 ±0.72 vs 35.79± 0.48, p value-0.003).

Though the worst ph in first 6 hour were similar in both group, base excess were significantly higher in control group compare to study group (p value-0.03). (**fig 4)**

DISCUSSION

Incidence of hypothermia among preterm neonates born at or below 1500 gm varies from 31 to 78% [2]. VLBW i.e. Very Low Birth Weight (<1500g) preterm infants are likely to become hypothermic despite the use of traditional techniques for decreasing heat loss [3]. For this reason the American heart association (AHA) and American Academy of paediatrics (AAP) guidelines for resuscitation 2005 recommended the use of additional warming techniques in these babies [4].

Optimal thermal treatment of preterm infant is a crucial aspect of care because hypothermia is a frequent problem in very preterm infants may influence outcome[3,5,6,7]. Hypothermia immediately after birth in extremely preterm infants was associated with reduced chances of survival in the Epicure study [3].

Hypothermia has been posited to predispose infants to infection due to lethargy, leading to aspiration pneumonia [16,17] Central nervous sys-tem depression also results in bradycardia, apnea and poor feeding [18,19]**.** The consequences of increased metabolism during hypothermia include hypoglycemia, hypoxia and metabolic acidosis [18,20]. In our study we took preterm infants <31 GA, 20 infants in each group, while Mathew et al [8] had taken 14 infants in each group <28 weeks of GA and Knobel et al [9] had taken 42 infants in each group <29 weeks of GA.

The mean birth weight in our study were 1030±250 and 900±263 in study and control group respectively while in Mathew et al mean birth weight were 842±55 and 838±42 in study and control group respectively and in Knobel et al mean birth weight were 918±259 and 850±253 in study and control group respectively.

There were no statistical difference in base line characteristics such as GA, birth weight, antenatal care and transfer time to NICU in our study and Mathew et al and Knobel et al study.

In our study we have taken below 31 weeks GA premature infants and we found significant higher temperature in study group compared to control group (35.83±0.48 vs 35.16±0.60, p value-0.0001). while previous study by Sunita et al and Githawala et al did not found significant difference in temperature in neonates 28-31 of GA. We found both vinyl and polyurethane bags to be equally effective in preventing hypothermia in extremely preterm infants.

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Knobel et al used polyurethane bags in less than 29 weeks GA preterm infants and found that it reduced occurrence of hypothermia and increased NICU admission temperature. They also proved that maintaining warmer delivery room helped but was insufficient in preventing hypothermia in preterm babies without polyurethane bags. Kent et al [10] observed improved admission temperature for infants less than 31 weeks GA by increasing ambient temperature in operation theatre and wrapping premature infants in polythene wrap. Ibrahim et al [11] and mc call et al [12] made similar observation. We maintained ambient Delivery room/operation room temperature and mean delivery room temperature >24 ^{o} C in both the groups and used both vinyl and polyurethane in the study group.

In our study we removed bags after 1 hour of initial stabilization and procedures in NICU and we measured axillary temperature at 1hour of admission which was significantly higher in study group (36.58 ±0.72 vs 35.79± 0.48, p value-0.003), compared to earlier study which showed similar rectal temperature in both wrapped and unwrapped group (sunita et a l [9.13] and Githawala et al [14]) where the removal of the wrap was on the admission into the NICU. There was increase in base excess in control group compare to study group, probably secondary to hypothermia but ph difference could not achieve statistical significant difference in both group like Mathew et al study which showed more acidosis in control group.

The maximal requirement of oxygen on ventilator or CPAP was significantly higher in standard care group in Mathew at al study but our study did not show statistical significant difference in both groups, and duration of oxygen requirement in days were significantly lower in study group but could not achieve statistical significance like Knobel et al study. We also observed that Incidence of CLD i.e. oxygen requirement at >28 days of life was statistically similar in both group (p=0.31).

We observed that requirement of surfactant and incidence of PDA which required treatment were similar in both groups (p=1). We also calculated wt loss and fluid requirement in first four days of life in both groups which was statistically similar in both group (p= 0.76, p=o.68). Occurrences of significant IVH, duration of NICU in days were similar in both groups statistically.

The main limitation of our study was small number of babies, however the sample size was sufficient to detect a Type I error of 0.05 and type II error of 0.20. Some studies have shown decreased oxygen requirement in wrapped babies which wasn't proved in our study. However we need larger trial to see this and then there could be a definite cost benefit advantage for these babies who are wrapped.

Placing infants in vinyl bags or polyurethane bags decreases heat loss by several mechanisms. There is decrease evaporative heat loss as evaporative water loss from skin surface that is not in contact with membrane contributes to high humidity in the air between membrane and skin. All areas of vinyl membrane and skin under membrane that faces heat source are heated through radiation causing heat gain to the neonate. This barrier also prevent convective heat loss from cold drought in the room. Absence of drying retains vernix caseosa which too decreases the evaporative heat loss [15].

We found that occurrence of NICU admission hypothermia in preterm infants below 31 weeks gestational could be reduced by placing them in polyurethane or vinyl bags immediately after birth.

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This study and others have also demonstrated that the occurrences of hypothermia in PT infants immediately after birth can be significantly reduced by use of occlusive covering, a simple non-invasive, inexpensive intervention.

Conclusion:

Neonates resuscitated in vinyl/polyurethane bags were warmer than neonates in conventional group. The difference in temperature was continued till 1 hr after NICU admission. VLBW babies do need additional warming techniques. Vinyl and polyurethane bag were safe and effective in prevention of hypothermia at birth in very low birth weight preterm neonates. Keeping the bag for 1 hour after admission, till procedures are completed would help in thermoregulation.

Though Vinyl/polyurethane bags group temperature was better compared to standard wrapping group, there was no difference in morbidity and mortality including duration of stay in NICU, We need larger trials to prove its superiority of early temperature management with vinyl/polyurethane bags compared to standard wrapping to improve outcome.

Key message

Vinyl and polyurethane bag were safe and effective in prevention of hypothermia and keeping the bag for 1 hour after admission, till procedures are completed would help in thermoregulation.

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Fig 1

Fig 2

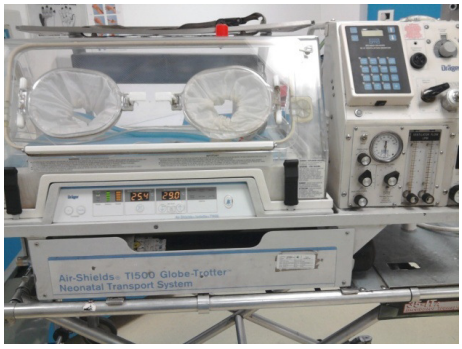

Fig 3

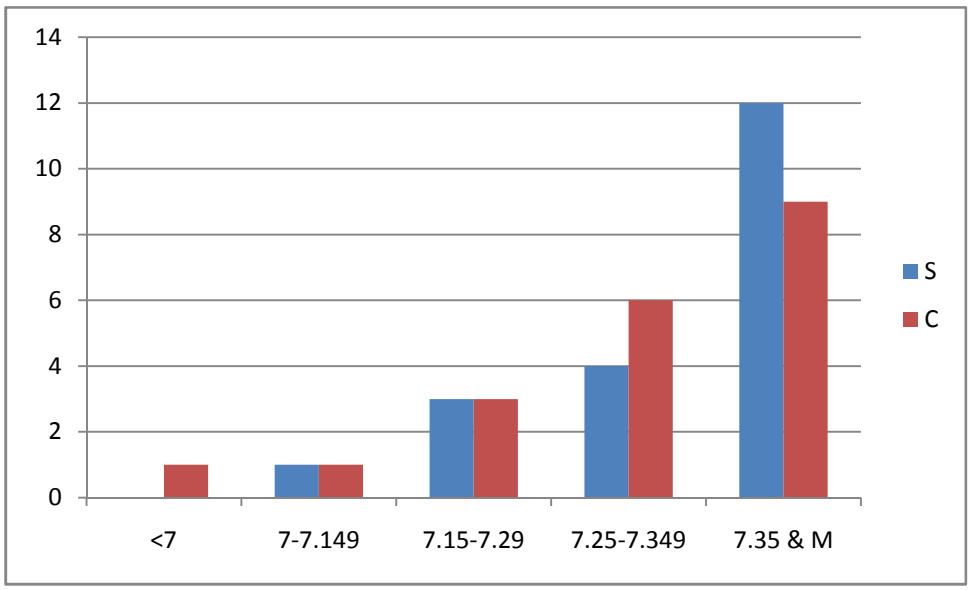

Fig 4 One baby had ph <7 in control group while none had in study group. There were 9 babies with ph <7.25, 4 were in study group and 5 were in control group. More no of baby's had ph>7.35 in study group compare to control group but could not achieve statistical significant (p value-0.11 NS).

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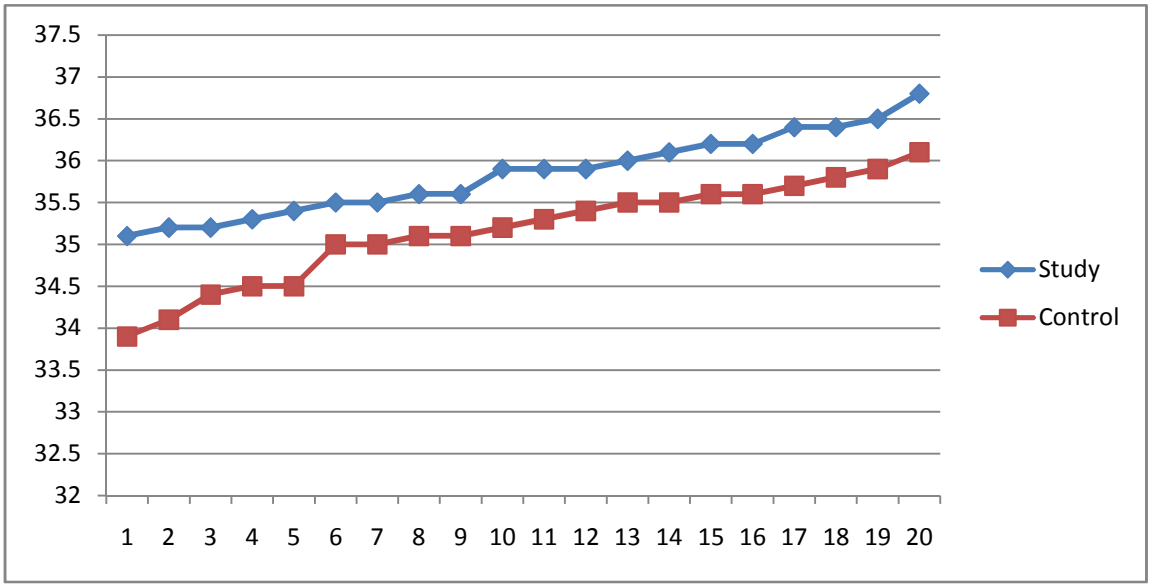
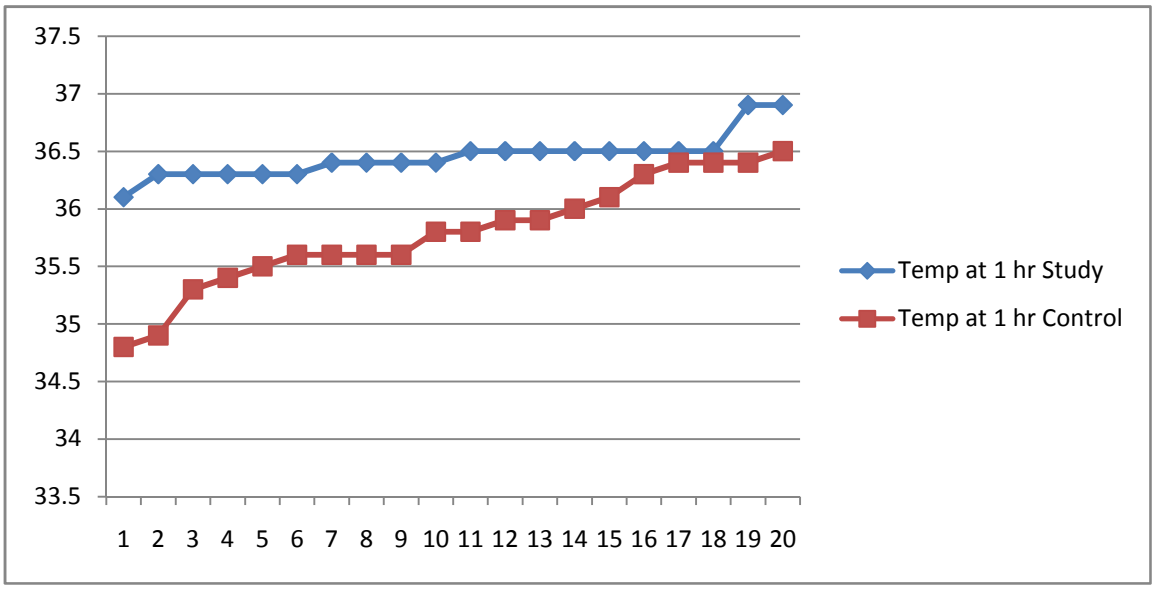


GRAPH-1 ADMISSION TEMPERATURE IN BOTH GROUPS (n=40)



GRAPH-2 TEMPERATURE AFTER 1 HOUR OF ADMISSION IN BOTH GROUPS (n=40).

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