



A Study to Assess the Effectiveness of Plastic Bag Wrapping in Preventing Sepsis among Preterm Neonates

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ABSTRACT

Septicaemia contributes to neonatal mortality and morbidity, especially in preterm and low birth weight infants in developing countries. Plastic bags covering the trunk and extremities of preterm and very low birth weight infants reduces septicaemia. The objective was to determine if placing preterm and low birth weight infants inside a plastic bag at birth causes reduction of sepsis incidence.

Keywords: Hypothermia, preterm, plastic bag, temperature regulation, sepsis.

INTRODUCTION

Annually, about 3.5 million infants die during the neonatal period worldwide¹. More than 75% of these neonatal deaths have been attributed to infection, birth asphyxia, hypothermia and congenital anomalies.² Hypothermia has long been recognized as a serious risk factor for sepsis in newborns, especially premature and low birth weight infants.³⁻⁶

Newborns are more prone for sepsis because of their immature immune system. The current thermal care guideline is based on NRP, which suggest to dry infants by placing them under a radiant warmer with dry, pre-warmed towels. Despite adherence to this guideline, the incidence of hypothermia and sepsis among premature infants remains high.

The Neonatal Resuscitation Program recommends the use of a plastic bag to prevent hypothermia in infants born <29 weeks gestation.⁷ The International Liaison Committee on Resuscitation Consensus statement recommends the use of a plastic bag in addition to standard techniques in the delivery room for preterm infants for prevention of hypothermia and sepsis.⁸

Plastic bags may be an affordable option for developing countries. The current trial was designed to test the hypothesis that use of low-cost plastic (polyethylene) bags starting at birth reduces sepsis among preterm infants.

This trial enrolled more mature and larger preterm infants than previously studied because in resource-limited settings these infants are at high risk of sepsis. This Practice is being used in under resourced countries when environmental

temperatures cannot be controlled, even in larger, term infants (Lester, Kiamani, & Cartledge, 2014).

MATERIALS AND METHODS

Study Design

In this single-centre randomized controlled trial conducted at the rural tertiary Hospital in Chidambaram, Tamilnadu, a standard thermoregulation care strategy (control group) was compared with a strategy including standard thermoregulation care plus wrapping of the newborn in a low-cost polyethylene bag (intervention group). Infants born at the hospital were eligible for inclusion if they were below 37 weeks of gestation at birth according to the best obstetrical estimate or those requiring only initial few steps of resuscitation.

Infants were excluded if they had an abdominal wall defect, myelomeningocele, other major congenital anomaly, other risk factors for sepsis or those requiring later steps of resuscitation. Neonates of the mother who are not willing to participate are also excluded.

In a 1:1 allocation and parallel design, infants were randomly assigned to 1 of the 2 treatment groups at birth. Randomization occurred at birth or within the first 10 minutes after birth. Twins and higher-order multiples were randomized individually. Randomization was blinded and done by using sealed numbered envelopes assigned by a random number generator. Study investigators kept the sealed envelopes and opened them at the birth of the infant. Blinding of the intervention was not possible.

Control Groups

Infants randomized to the control group were delivered and immediately set on their mother's abdomen, then dried with blankets and stimulated on the mother's abdomen while the cord was cut and placenta delivered. If the infant was delivered by cesarean section, the infant was initially dried and stimulated under a radiant warmer in the

operating room and then transferred to the nursery in the labor and delivery unit.

Intervention Group

Infants randomized to the intervention group received the same care, except they were placed inside a plastic bag (nonmedical) low-cost, linear low-density polyethylene bag covering the trunk and extremities. The head of the baby was covered with a cap.

Outcomes

Prespecified primary outcomes on patients admitted to the NICU included seizures during the first 24 hours after birth, sepsis (monitored using CRP and WBC counts), metabolic abnormalities including glucose levels (CBG) and serum calcium levels, weight gain, initiation of feeds and death before discharge.

RESULTS

Majority of the cases were between 32 to 36 weeks (>50%). Very few cases were between 26 to 28 weeks (7%). In the present study, there is no significant difference in the number of male and female neonates. There were 28(56%) males among cases and 30 (60%) males among controls. There were 22 (44%) females among cases and 20 (40%) females among controls. In our present study, the mean weight of the babies in study group is $1.8542 \pm .44245$ kg and $1.9042 \pm .44278$ kg in the control group. The mean weight of the babies among gestational age 32 to 36 weeks is 2.141 kg.

There is an incidence of 42% positive CRP levels in control group when compared to 8% in study group. The levels of WBC were elevated in 12% of study group when compared to 38% in control group. The incidence of hypoglycemia is 6% in study group when compared to 28% in control group.

The incidence of hypocalcemia is 22% in control group when compared to 6% in study group. The incidence of seizures is nil in study group when compared to 14% in control group. Majority of

babies (68%) were started on feeding <15 hrs in study group when compared to 24% in control group. The weight gain of babies were adequate in 80% of babies in study group when compared to 28% in control group. There is no incidence of mortality in study group when compared to 2% in control group.



Picture taken after getting consent from the parents



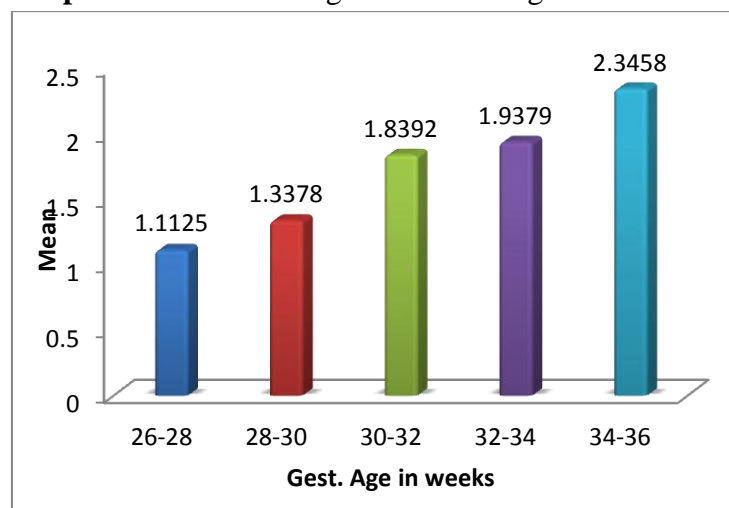
Plastic sheet used in the study

Table: 1 Gestational Age vs Birth Weight mean

Gest. Age	N	Mean	Std. Deviation	F	Sig.
26-28	4	1.1125	0.16520	54.597	0.000
28-30	18	1.3378	0.22683		
30-32	24	1.8392	0.31690		
32-34	28	1.9379	0.21619		
34-36	26	2.3458	0.22897		
Total	100	1.8792	0.44109		

The mean weight of the babies among gestational age 32 to 36 weeks is 2.141kg.

Graph : 1 Gestational Age vs Birth Weight mean



DISCUSSION

This trial shows that placement of the trunk and extremities of preterm infants in a plastic bag and covering the head with a cap at birth or shortly after birth decreased incidence of sepsis.

Limitations

- 1) The short duration of the intervention.
- 2) The inaccuracy of pregnancy dating, which is common in low- resource countries and may explain the high proportion of infants 2500 g birth weight.
- 3) We cannot exclude the possibility that term infants were enrolled.
- 4) The lack of control of the environmental temperature in the delivery rooms and resuscitation areas. The hospital did not have central air-conditioning or heating, and strict control of the ambient temperature was not possible.

Vohra et al and Vohra et al., found that wrapped infants <28 weeks gestational age had higher mean rectal admission temperatures and reduction of sepsis.⁹

Knobel et al., recently showed similar results with polyurethane wrapping. This appears to be very important in extremely premature infants.¹⁰

Larger Preterm infants also have increased incidence of sepsis after birth, and the current trial demonstrates that plastic bags may also reduce sepsis in these infants. The relatively high prevalence of sepsis, even in the larger preterm infants enrolled in the current trial suggests that these infants may benefit from placement inside a plastic bag shortly after birth.

CONCLUSION

Despite decades of research on prevention of sepsis, neonatal septicaemia remains a common global problem, contributing to needless deaths. Our review provides strong support for the efficacy of plastic wraps to reduce incidence of sepsis following a hospital delivery in neonates of all gestational ages.

Plastic wraps are available globally, cheap, are easy to use and carry a low risk of adverse events. Further research is required to assess their role outside hospital settings (for example, as part of birth kits), investigate morbidity or mortality decreases, as well as investigate instances other than delivery where they are useful;

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