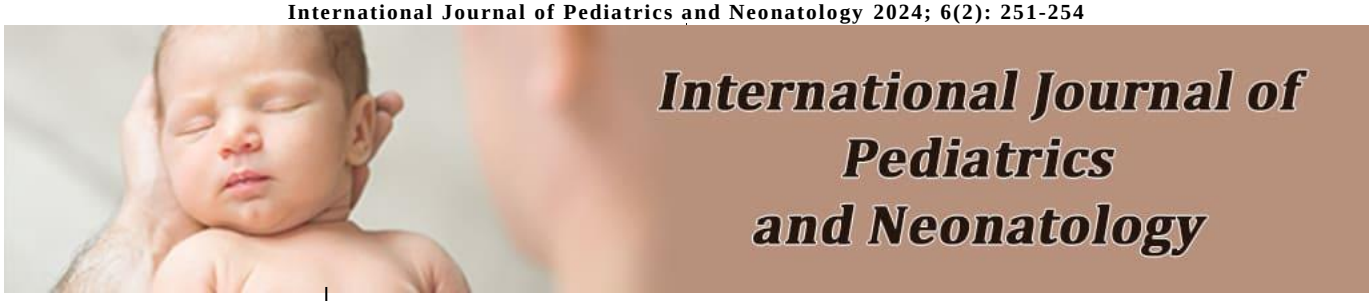

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A study on effectiveness of quality improvement interventions in reducing hypothermia in very low birth weight new-borns on admission to neonatal intensive care unit

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Abstract
Background: Hypothermia in new-born when the body temperature drops below 36.5 °C. Premature infants have higher risk of hypothermia. For each drop in 1 °C of body temperature, mortality rate is increased by 28% & rate of late onset sepsis is increased by 11%. The incidence of hypothermia in Very Low Birth weight (VLBW) infants on admission to NICU ranges between 31 to 78%.
Aims and Objectives: To study the effectiveness of quality improvement interventions in reducing hypothermia in very low birth weight infants on admission to neonatal intensive care unit and to evaluate the outcome of the babies before & after quality improvement at a tertiary care hospital in Southern Rajasthan.
Materials and Methods: This was a Prospective Observational study conducted Tertiary Care hospital. The study included preterm infants below 1500 gm weight born at the Obstetric department of the hospital. The study was done in 2 phases. An Observation phase of 3 months and implementation phase of 6 months (3 cycles).
Results: A total of 100 babies during observation and 200 babies during implementation phase were studied. Mean admission temperature in Plan Do Study Act (PDSA) phase increased significantly to 36.53º C from 35.25ºC in observational phase. The incidence of moderate hypothermia decreased from 69% to 22.37%. Similarly, the incidence of normal temperature increased from 2% to 27.63% (p <0.001). complications like IVH (4% Vs 13%, $p < 0.01$), Late onset neonatal sepsis (23.5% Vs 41%, $p < 0.05$) showed significant reduction. Mortality reduced from 23% to 17%.
Conclusion: Quality improvement method using the WHO-POCQI model, is a very cost-effective approach in reducing admission hypothermia at NICU in pre-term babies in a resource limited setting, and further decreasing the morbidity associated with it.

Keywords: Hypothermia, very low birth weight newborn, Quality improvement interventions

Introduction
Hypothermia after birth is a particularly significant problem in Premature Newborns. In India, Hypothermia on admission to Neonatal Intensive Care Unit (NICU) was associated with mortality rate twice that of infants admitted with normal temperature. The incidence of hypothermia in Very Low Birth weight (VLBW) infants on admission to NICU ranges between 31 to 78% [1].
Hypothermia in newborn is called when the body temperature drops below 36.5°C (97.7°F). The World Health Organization (WHO) has recommended that the temperatures of newborns be maintained between 36.5 and 37.5°C. (97.7 - 99.5°F) [2].
1.Cold stress or Mild Hypothermia: 36.0 to 36.4° C (96.8 to 97.5° F); 2. Moderate Hypothermia: 32.0 to 35.9°C (89.6 to 96.6° F); 3. Severe Hypothermia: below 32 °C (89.6° F). Evaporation, Conduction, Radiation and Convection are the major means of heat loss in newborns.[2] Compared with term infants, premature infants have- A higher ratio of skin surface area to weight, highly permeable skin which leads to increased trans-epidermal water loss, decreased subcutaneous fat with less insulative capacity, less-developed stores of brown fat and decreased glycogen stores, poor vasomotor control, challenges with adequate caloric intake to provide nutrients for thermogenesis & limited oxygen delivery if pulmonary conditions coexist [2].

Hypothermia can lead to Hypoglycaemia, Metabolic acidosis, Poor weight gain, Hypoxia, Apnoea, Persistent pulmonary hypertension (PPHN), Sepsis, Coagulopathy, Neurological Injuries [3].

For each drop in 1^0 C of body temperature, mortality rate is increased by 28% & rate of late onset sepsis is increased by 11% [4].

Warm chain is a series of interlinked steps to prevent hypothermia in neonates - Keep the room warm, Skin to skin contact (STS), Warm resuscitation, Immediate drying, Exclusive breastfeeding, Postpone bathing, Appropriate clothing, Extra clothing in winter, Rooming in & Bedding in, Warm transportation, Training & awareness [2].

This study was conducted at a tertiary care centre to study the effectiveness of quality improvement interventions in reducing hypothermia in preterm infants on admission to neonatal intensive care unit and to evaluate the outcome of babies (including morbidity & mortality) before & after quality improvement.

Materials and Methods

This was a Prospective Observational study conducted at NICU of a Tertiary Care hospital in Southern Rajasthan. After getting ethical clearance data was collected for first 3 months (january-2022 to march-2021) before quality improvement initiative, and then from April 2022 with quality improvement initiative. The study included preterm infants below 1500 gm weight born at the Obstetric department of the hospital excluding infants with Gross congenital malformations and infants requiring surgical intervention. The study was divided in 2 phases. During an observation period of three months, a dedicated paediatric resident observed the delivery room activities. A root cause analysis was done via a Fishbone diagram to find out contributing factors of hypothermia. On the basis of observations in the delivery room activities a Pareto chart to prioritize our interventions was constructed to identify those few important practices that needed to change. The Pareto chart revealed that 80% of the problem of hypothermia was predominantly due to 20% of the causes such as lack of knowledge and awareness in nursing staff, lack of materials like caps/cling wraps and improper use of linen.

Diagram

Once problems were identified, its magnitude, and its possible causes, a multidisciplinary thermoregulatory Quality Improvement (QI) team was formed comprising of a Senior Neonatologist, nursing-in-charge, staff, resident doctors, transportation team, and a team leader, who were each assigned a specific duty. Total 3 Plan-Do-Study-Act (PDSA) cycles were planned to test and adapt possible solutions to the contributing factors of hypothermia as shown in Table 1.

Table 1: PDSA cycles

PDSA cycle	Plan	Do	Study	Act
1-4-2022 to 31-5-2022 (2 months)	Education of medical and nursing staff	Taking Lectures on hypothermia, re assessing knowledge after the lectures via questionnaire – Teaching material: (pamphlets) distributed to staff and posters kept in each NICU/ transport ambulance	Mean Temp increased from 35.25 ºC to 36.15 ºC	Adopt the PDSA cycle and continue with it
	Increasing the ambient temperature of Delivery room	Nurses of delivery room were encouraged to keep radiant warmer on, to switch off the AC, try to maintain temp to 25 ◦C. Digital Thermometer made available, motivated staff to use it always	Moderate Hypothermia decreased from 69% baseline to 46%.	
	Introducing polyethylene bags	polyethylene bags were made available.		
1-6-2022 to 31-7-2022 (2 months)	Using Caps, Polyethylene bags, linen	Caps (of all sizes) and cling wraps made available Staff taught how to apply cling wrap, warm linen. Staff was taught how to put baby in bags after delivery before drying.	Mean Temp increased from 36.15ºC to 36.38ºC Moderate Hypothermia decreased from 46% to 36%.	Adopt the PDSA cycle and continue with it.
1-8-2022 to 30-9-2022 (2 months)	Use of Transport Incubator Co-ordinated team work	Transport Incubator was repaired – Use of transport incubator was demonstrated to staff Team was informed before shifting, Radiant warmer was put on manual mode 100% heater output.	Mean Temp increased from 36.38 ◦ C to 36.5 Moderate Hypothermia decreased from 36% to 22%	Adopt the PDSA cycle and continue with it.

All data was prospectively collected, including the following information like date of birth, birth weight, gestational age, sex, Apgar score, axillary temperature taken immediately after admission to the NICU, and ambient air temperature in the NICU. Outcome parameters included the incidence of Hypothermia, Mortality and Morbidity (i.e., Patent Ductus Arteriosus, Hyaline Membrane disease, Bronchopulmonary dyspasia, Sepsis and Pulmonary Haemorrhage, Necrotising enterocolitis, Intraventricular hemorrhage when >grade 2, Retinopathy of prematurity stage 3&4,) & ultimate disposition (discharge or death) among all preterm VLBW infants.

Predictor variables was as follows: maternal and intrapartum variables (age, race, prenatal care, antenatal steroids, spontaneous labour, multiple births, delivery mode, maternal or uterine infection, prolonged rupture of membranes (PROM and hypertension); Infant characteristics (gender, birth weight, gestational age) and delivery room variables (Apgar scores, resuscitation including oxygen administration, CPAP, bag-mask ventilation, chest compressions and epinephrine administration). Low Apgar scores were defined as an assigned value <7. Appropriate Statistical tests were applied for the collected data.

Results

During the observation period of 3 months a total of 100 babies and during the implementation phase a total of 200

babies were studied. PDSA 1 consisted of 52 babies, PDSA 2 included 68 babies and PDSA 3 included 76 babies. The babies were comparable in baseline parameters like Sex, Gestational age, Mean birth weight, APGAR score at birth.

Mean Axillary temperature at admission was 35.25±0.44 in observation phase and during PDSA 1 it was 36.15± 0.39, PDSA 2 it was 36.38±0.31, PDSA 3 36.53±0.23(Table 2)

Mean admission temperature in PDSA phase increased significantly to 36.53º C from 35.25ºC in observational phase.

During Observation phase percentage of babies with normothermia, mild hypothermia and moderate hypothermia was 2 (2%), 29 (29%), 69 (69%) respectively.

During PDSA 1, 6 (11.54%) babies were normothermic,22 (42.31%) mildly hypothermic and 24 (46.15%) babies were moderately hypothermic.

During PDSA 2, 12 (17.65%) babies were normothermic, 31 (45.59%) mildly hypothermic and 25 (36.76%) babies were moderately hypothermic.

During PDSA 3, 21 (27.63%) babies were normothermic, 38 (50%) mildly hypothermic and 17 (22.37%) babies were moderately hypothermic. (Table 3)

The incidence of moderate hypothermia decreased from 69% to 22.37% (observational phase to PDSA 3). Similarly, the incidence of normal temperature increased from 2% to 27.63%. p <0.001.

On comparing the various complications of hypothermia in between the Observation and Implementation phase, it was seen that there was no significant difference in rates of hypoglycaemia, respiratory distress, NEC and mortality with reduction in admission hypothermia. However, complications like IVH (4% Vs 13%, p < 0.01), Late onset neonatal sepsis (23.5% Vs 41%, p < 0.05) showed significant reduction in Implementation phase as compared to Observation phase. Also, respiratory distress decreased from 45% to 30% in the implementation phase. (Table 4)

Comparing the Outcome between Observation phase 77 (77%) babies were discharged and 23 (23%) babies died, whereas during implementation phase 166 (83.0%) babies were discharged and 34 (17.0%) babies died. Number of deaths reduced from 23% to 17%, though was statistically non-significant. (Table 5).

Table 2: Comparison of Mean Admission Temperature in Observation Phase and in Different PDSA cycles of Implementation Phase

	Mean	SD
Observation Phase(n=100)	35.25	0.44
Implementation Phase(n=200)		
PDSA 1(n=52)	36.15	0.39
PDSA 2(n=68)	36.38	0.31
PDSA 3(n=76)	36.53	0.23

Table 3: Percentage of normothermia, hypothermia and hyperthermia in observation phase and different PDSA cycles

	Normal (>36.5 37.5 °C)	Mild Hypothermia (36–36.5 °C)	Moderate Hypothermia (32–36 °C)	Hyperthermia (>37.5 °C)
Observation phase (n=100)	2 (2%)	29 (29%)	69 (69%)	-
PDSA 1 (n=52)	6 (11.54%)	22 (42.31%)	24 (46.15%)	-
PDSA 2 (n=68)	12 (17.65%)	31 (45.59%)	25 (36.76%)	
PDSA 3 (n=76)	21 (27.63%)	38 (50%)	17 (22.37%)	

Table 4: Comparison of complications of hypothermia between Observation phase and Implementation phase

Complications	Observation phase	Implementation phase	P-value
Respiratory distress	45 (45%)	60 (30%)	p>0.05
IVH	13 (13%)	8 (4%)	p<0.01
PDA	4 (4%)	2 (1%)	p>0.05
NEC	18 (18%)	20 (10%)	p>0.05
LONS	41(41%)	47 (23.5%)	p<0.01
Hypoglycaemia	11 (11%)	30 (15%)	p>0.05
ROP	7 (7%)	18 (9%)	p>0.05
Metabolic Acidosis	38 (38%)	52 (26%)	P<0.01

Table 5: Comparison of Outcome between Observation phase and Implementation phase.

Outcome	Observation Phase	Implementation Phase	P value
Discharge	77 (77%)	166 (83.0%)	>0.05
Death	23 (23%)	34 (17.0%)	

Discussion

The present study "A study of effect of reduction in hypothermia by quality improvement on morbidity and mortality of preterm newborns admitted in NICU of a tertiary care centre in southern Rajasthan" was conducted in NICU of Tertiary care centre of Southern Rajasthan, from January 2022 to August 2022. Our study included a total of 300 newborns, 100 in the observation phase, 200 during the implementation phase (PDSA 1, 2 and 3). The baseline characteristics of our study population in terms of gender, birth weight, gestational age, mode of delivery, duration of transport, any support requirement in form of intravenous fluids/oxygen requirement, was found to be similar in different phases of the study. Our study showed incidence of moderate hypothermia at admission during observation period was 69% (Table 3) which was similar to a study conducted by Datta *et al* [5] to be 70% whereas a study from AIIMS by Sivanandan *et al* [6] showed moderate hypothermia of about 50%. The variation could be explained by differences in Delivery room conditions,

labour room to NICU distance and methods of transportation. We have conducted our study mostly in rainy season, and sustainability phase was continued up to winter season. It has been well known that seasonal variation effects the incidence of hypothermia. A study in northern India by Darmstadt *et al* [7] has reported a 70% incidence of hypothermia among new borns during January to March, 20% during April to June, 32% in July to September and 55% in October to December. There was a reasonably good compliance with the various interventions we introduced during the study. There was drastic increase in the use of neonatal caps, cling wraps, linen and polyethylene bags after their respective PDSA cycles. The Cochrane review in 2004 and previous studies by Datta *et al* [5] and Patodia *et al*[8] have also shown that using caps, polyethylene bags and cling wraps have been quite effective in preventing hypothermia in especially preterm babies. We also evaluated many complications related to hypothermia, and it was quite reassuring to see that with decrease in hypothermia there was significant decrease in complications like IVH, LONS and Metabolic acidosis. There was also mild decrease in NEC rates from 18% to 10%, but it was not statistically significant. Other complications like hypoglycaemia, respiratory distress and overall outcome in form of mortality was almost similar throughout the study (Table 4). Laptook *et al* [9] also showed significant decrease in LONS with decrease in hypothermia, however there was no effect on incidence of IVH and NEC.

Some studies like Datta *et al* [5] and Patodia *et al* [8] have shown significant reduction in mortality as well with decrease in hypothermia, however our study was not able to demonstrate so (Table 5). This could be due to a shorter study period leading to insufficient power to detect a small difference in outcome and may be after sustaining our QI efforts for a longer period we might be able to demonstrate a decrease in overall mortality in the long run. Also, the babies shifted to our NICU, being a tertiary centre, were relatively more sick babies, thus we could have a higher morbidity and mortality which cannot be just attributed to hypothermia.

Conclusion

The study successfully demonstrates that Quality improvement method using the WHO-POCQI model, is a very cost-effective approach in reducing admission hypothermia at NICU in pre-term babies in a resource limited setting, and further decreasing the morbidity associated with it, thus highlighting the importance of maintaining euthermia not only in delivery rooms, but also during transportation. Hence, QI studies should be encouraged in other hospitals of similar settings, where hypothermia is still under recognized and under-managed. We have also been able to sustain our QI efforts, and seeing the positive results, are further motivated to continue the sustainability phase.

Conflict of interest: None

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