Targeted Quality Improvement Project Dramatically Reduced Admission Hypothermia in Very Low Birth Weight Infant in China: A Multicentre Study

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Abstract

Background: Hypothermia is still a common problem and is associated with increased mortality and morbidity in preterm infants, especially in China. The objective of this study was to evaluate the efficacy of a targeted quality improvement (QI) project of hypothermia preventive measures in very low-birth weight (VLBW) infants in 3 tertiary neonatal intensive care unit (NICU) in China.

Methods: Based on the literature, our preliminary findings and the needs of each unit, our team decided to focus efforts on equipment (transport incubator, pre-warmed hats and polyethylene wrap), team training and education, as well as temperature documentation and workflow. The primary outcome measure was the incidence of hypothermia, defined as temperature (rectal temperature) below 36.5°C on admission to the NICU. This quality improvement (QI) initiative used the rapid cycle Plan - Do - Study - Act (PDSA) approach. The outcomes of pre-quality improvement (pre-QI) group (January 1, 2018– December 31, 2018) were compared with post-QI group (January 1, 2019–December 31, 2019). The study enrolled preterm infants born at less than 32 weeks' gestation with very low birth weight less than 1500 g born at 3 academic, tertiary-care hospitals including Shandong Provincial Hospital, The First Affiliated Hospital of Shandong First Medical University, LiaoCheng People's Hospital Affiliated to Shandong First Medical University between January 2018 and December 2019.

Results: A total of 636 VLBW infants were included in this analysis, of which 235 infants (36.9%) were included in the pre-QI group and 295 infants (46.4%) in the post-QI group. The incidence of hypothermia decreased significantly from 92.3% to 62% ($P < 0.001$), and the mean body temperature on admission to NICU increased significantly from 35.5°C to 36°C ($P < 0.001$). There were one cases (0.3%) of neonatal hyperthermia. Infants in the post-QI group had lower rates of mortality (16.1% vs 8.8%, $P = 0.01$).

Conclusions: Targeted interventions can dramatically reduce admission hypothermia and improve the outcome of VLBW infants in China.

Background

Preterm infants have difficulty maintaining body temperature after birth due to the immature physiological development, especially among very low-birth weight (VLBW) infants [1, 2]. The incidence of hypothermia on admission to the neonatal intensive care unit (NICU) in VLBW preterm infants is 31%-78% [3, 4]. With the development of the economy and intensive care technology, the survival rate of preterm infants is getting higher and higher in China, but there is still a big gap compared with that in the developed nations. Cao yun et al [5]. reported that the estimated overall mortality was 23.9%. Compared with Canada, the case fatality rate for each birth weight stratification was higher in VLBW infants in China [6]. Since January 1, 2018, our neonatal clinical research team has established China regional neonatal collaboration network, the Shandong Neonatal Network (SNN). The SNN covers more than 100 million people. The SNN prospectively collected neonatal data from participating units. During this process, we found that the incidence of neonatal admission hypothermia was quite high. So, a

retrospective analysis was conducted on VLBW infants born between January, 1, 2017 and December, 31, 2017 to determine key drivers of change. The incidence of admission hypothermia (AH) was 87.9% in VLBW infants among the 28 NICUs in 2017 [7]. And then in 2018, we conducted a prospective analysis and found that AH was 88.2% in VLBW infants between January 2018 and December 2018, and AH was closely related to their mortality, especially in moderate to severe hypothermia cases [4, 8, 9].

Internationally, the thermoregulation guidelines involved multiple modalities divided into four phases: pre-delivery preparation, resuscitation, transfer, and NICU admission [10–14]. But the proportion of admission hypothermia was still higher in clinical practice. Based on recent studies [15–18], after initiating quality improvement (QI) project, the incidence of AH significantly declined and more and more evidence-based QI measures have showed successful. However, there was few studies on the current situation of hypothermia in preterm infants in China [19], especially lack of multicenter and large sample studies.

Our preliminary study proved that there was a negative correlation between the incidence of AH and the number of measures implemented to prevent hypothermia, as well as what were the key drivers of QI project implementation [7]. Therefore, combined with international experience, we hypothesized that the implementation of the targeted QI bundle could reduce the incidence of AH and improve outcomes in VLBW infants. Since January 1, 2019, we established Shandong Multicentre Study Coordination for Admission Hypothermia in China and initiated a QI project to prevent hypothermia in VLBW infants admitted to all participating NICUs. Our primary goal was to prevent AH in VLBW infants by preventing excessive heat loss in the delivery room and transportation process. Our target is to maintain the admission temperature between 36.5 °C and 37.5 °C to the maximum extent possible. In order to achieve this goal, we standardized delivery room management and NICU admission processes for all VLBW infants. The aim of this study was to evaluate the change of the incidence of AH of VLBW infants born at 3 homogeneous academic, tertiary-care hospitals participating SNN, and to analyze their mortality and morbidity before and after quality improvement.

Methods

Setting

This prospective, multicentre and time-series cohort study was carried out over a period of 24 months, from January 1, 2018, to December 31, 2019, in three homogeneous NICUs.

Participants

The study population included all inborn infants with a birth weight (BW) less than 1500 g and gestational age (GA) less than 32 weeks who were admitted to the NICUs. Infants who were out-born, who had redirection of intensive care including congenital anomalies, who were death in the delivery room and whose mother had a fever during delivery (temperature ≥ 38 °C) were excluded. Those three hospitals are teaching hospital located in Shandong, China with an adjacent level 3 regional NICU with averages of 36 beds. The NICUs of the three hospitals received an average of about 1,623 newborns per year, of which

VLBW infants were about 500 cases (30.7%). The average ratio of nurses to bed and physician to nurse was 1:2.2 and 1:1.9, respectively.

Interventions

QI methodologies, the fishbone diagram, were used to identify and prioritize the contributing factors (Fig. 1). Based on these findings, keeping warm and improve team training and education were identified as key drivers of change. To meet these two objectives, a temperature bundle management was designed with 11 key elements (Table 1). Briefly, bundle components included the use of radiant warmers, plastic wrap, thermal mattresses and transport incubator and increased room temperature and pre-warmed hat and blanket. Bundle also emphasized accurate documentation of temperature at each point in time. The bundle were implemented using the plan, do, study and act (PDSA) framework [17].

Table 1
Temperature bundle management

Objective	Intervention
Keep warm	Ambient temperature at 25 °C
	Switch on radiant warmers and set it to maximum heat output
	Infant immediately after birth wrapped with a polyethylene wrap without drying
	Infant quickly weighed after being placed in a pre-warmed blanket
	A pre-warmed hat is placed on the head
	thermal mattresses
	Infant transported with a heated transport incubator
improve team training and education	Document temperature (10 min after birth, arriving at the NICU, soon after every 30 min)
	Make temperature measurement standard
	Training and assessments on temperature measurement for nurses
	Monthly chart reporting on hypothermia in preterm infants on admission to the NICU

QI Activities

PDSA1 (January 2019 - March 2019)

After a panel discussion and approval by the Ethics Committee of Shandong Provincial Hospital, we began to implement the temperature management protocol in January 2019. The implementation contents are as follows: 1) Ambient temperature at 25 °C; 2) Turn on the heating mode of the air conditioner and set the temperature above 25 °C; 3) Pre-warmed caps (stockinette or woollen) was placed

on the head; 4) Infant quickly weighed after being placed in a pre-warmed blanket; 5) Document temperature (10 min after birth, arriving at the NICU, soon after every 30 min).

PDSA2 (April 2019 - June 2019)

After repeated training, we moved on to the second stage. All infant immediately after birth wrapped with a polyethylene wrap (measuring 30 cm × 40 cm, with a T-shirt-type opening and a border that allowed closure at the other end) without drying; We chose to use a thermal mattress made of food-grade sodium acetate; Our team made temperature measurement standard: All nurses in the NICU needed to be trained and evaluated for temperature measurement.

PDSA 3 (July 2019 - December 2019)

Due to the high cost of transshipment warm box, so the final implementation. The temperature of the transport incubator was maintained at about 35 °C; A debriefing check list was created for infants with admission hypothermia and were audited and feedback weekly. Control charts for hypothermia were reviewed every month.

Implementation

After the establishment of SNN, we set up the Shandong Multicentre Study Coordination for Admission Hypothermia. For the convenience of communication, we leave contact information with each other, such as telephone number, QQ number, email address, WeChat ID, and set up WeChat group. The team is responsible for reviewing recommendations and initiating a preventive hypothermia program. The team is composed of the department director, medical team leader, a neonatologist, the unit clinical nurse specialist, and charge nurse of each centers. The department director is responsible for the research design, the discussion and development of the diagnostic criteria and the quality control plan. The medical team leader and the neonatologist are responsible for implementing the test plan, collecting data, recording temperature and verifying the implementation of various measures. The charge nurse is responsible for temperature measurement at all points in time and for quality control during the temperature measurement process. We have weekly department staff meetings and monthly online meetings. The medical team leader prepared a power point presentations to report to the team on the causes of hypothermia. In order to ensure the implementation of these measures in place, our team has developed a manual list, an implementation list and a verification list. In monthly online meetings, the department directors can follow up on unfinished work, so that medical team leaders can be urged to better complete these measures.

Sample size

According to literature [15–19], set $\alpha = 0.05$ (bilateral) and degree of assurance = 0.8. The software PASS11 was used to calculate 225 samples before and after quality improvement. We assumed that 10% of the enrolled patients are missing key outcome indicators in this study, with a sample size of 250 before and after quality improvement.

Outcomes

Infants born between January 2018 and December 2018 constituted the pre-quality improvement (pre-QI) group and infants born between January 2019 and December 2016 were classified as the post-quality improvement (post-QI) group. All data were obtained from SNN database. AH was defined as rectal temperature $< 36.5^{\circ}\text{C}$, measured by digital thermometer (OMRON, MC-347), when the newborn arrived at the NICU. We developed a standard worksheet to measure temperature. The worksheet mainly recorded the time point of temperature measurement (10 min after birth, arrival in the NICU, and then every 30 min until the temperature rising to 36.5°C), the value and the measurement time. Comparisons were made with historical controls delivered in 2018 from the existing SNN database.

The primary outcome was the monthly proportion of newborns with AH and the mean admission temperature. We calculated this proportion by taking the monthly number of VLBW infants with a hypothermic event and dividing it by the monthly total number of VLBW infants admitted to NICUs after birth. The secondary outcomes were to compare the morbidity of severe intraventricular haemorrhage (IVH) (grades III and IV, according to Papile classification), necrotizing enterocolitis (NEC) (Bell grades II and III), pulmonary haemorrhage, severe bronchopulmonary dysplasia (BPD), retinopathy of prematurity (ROP) (grades $\geq$ III) and in-hospital mortality. Balancing measures were the proportion of newborns with admission hyperthermia (as defined by a rectal temperature $> 37.5^{\circ}\text{C}$). Additionally, in order to ensure that the ambient temperature is maintained above 25°C , we used the same digital laser infrared thermometer for measurement and made correction once a month to avoid errors.

Statistical methods

The statistical analyses were conducted using SPSS v. 25.0 (SPSS Inc., Chicago, Illinois). The monthly rate of admission hypothermia was tracked by using statistical process control charts (QI Macros). Demographic data are expressed as the means [$\pm$ standard deviations (SDs)] or percentages. In the univariate analysis, we used the t tests, chi-square tests or Fisher's exact tests. We then evaluated the odds ratios (ORs) according to admission temperature using a multivariate logistic regression analysis, with adjustment for factors that had a $P < 0.1$ in the univariate analysis. A 2-sided 0.05 level of significance was used for all analyses. The manuscript was prepared using the Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0) Guidelines [20].

Results

A total of 636 infants with a BW < 1500 g and GA < 32 weeks were enrolled in the study on their day of birth; 58 out-born infants were excluded. Additionally, 11 infants with congenital anomalies and/or redirection of intensive care [limited care (not intensifying medical treatment) or withdrawal of care], 10 infants with maternal pyrexia and 27 infants with missing data were excluded. The remaining 530 infants were included in this analysis (Fig. 2). Of these, 235 were born in the pre-QI group and 295 in the post-QI group. The final cohort had a mean BW and GA of (1119.1 ± 228) g and (28.6 ± 1.7) weeks, respectively.

The new thermoregulation protocol was introduced into practice in January 2019. The incidence of AH decreased dramatically in the post-QI group, with a reduction from 92.3–62% ($p < 0.001$). The mean admission temperature had also significantly increased to 36.0 ± 0.7 °C from 35.5 ± 0.7 °C ($P < 0.001$). Although the numbers were small, one infant (0.3%) within the intervention group had admission hyperthermia (Table 2). The rate of AH was tracked by the control chart (Fig. 3). The control chart revealed that Central line was shifting down during post-QI phase. The baseline characteristics of infants in the intervention group were similar to the historical controls in 2018. (Table 2).

Table 2
Comparison of Maternal and Infant Characteristics

	Pre-QI (n = 235)	Post-QI (n = 295)	<i>P</i> *
GA [weeks, $\bar{x} \pm s$]	28.8 ± 1.7	28.5 ± 1.6	NS
BW [g, $\bar{x} \pm s$]	1138 ± 228	1103 ± 228	NS
Sex (boy)	126 (53.6)	157 (53.2)	NS
Caesarean section	175 (74.5)	208 (70.5)	NS
Multiple birth (twins or more)	42 (17.9)	71 (24.1)	NS
Apgar score at 1 min < 7	111 (47.2)	154 (52.2)	NS
Apgar score at 5 min < 7	48 (20.4)	69 (23.4)	NS
Maternal hypertension	93 (39.6)	112 (38.0)	NS
GDM	25 (10.6)	39 (13.2)	NS
PROM	60 (25.5)	78 (26.4)	NS
Admission temperature [°C, $\bar{x} \pm s$]	35.5 ± 0.7	36 ± 0.7	< 0.001
Hypothermia	217 (92.3)	183 (62.0)	< 0.001
Hyperthermia	–	1 (0.3)	–
Data are presented as the mean or n (%).			
* <i>t</i> test or chi-square test.			
Abbreviations: NS, not significant; GA, gestational age; BW, birth weight; PROM, premature rupture of membranes; GDM, gestational diabetes mellitus.			

There were no significant differences in the morbidity of other secondary outcomes, namely severe IVH, NEC, pulmonary haemorrhage, severe BPD, LOS, and ROP. However, there was a significant reduction in the incidence of in-hospital mortality in the post-QI group when compared to the pre-QI group ($P = 0.01$) (Table 3). There were no differences in the incidence of hypothermia and neonatal outcomes between the plan-do-study-act (PDSA) cycles (Table 4).

Table 3
Outcomes of infants in the QI intervention group compared with historical controls

	Pre-QI (n = 235)	Post-QI (n = 295)	<i>P</i> *
Mortality	38 (16.1)	26 (8.8)	0.01
Pulmonary haemorrhage	22 (9.4)	20 (6.8)	NS
BPD	28 (11.9)	28 (9.5)	NS
IVH	31 (13.2)	38 (12.9)	NS
NEC	13 (5.5)	14 (4.7)	NS
LOS	87 (37.0)	90 (30.5)	NS
ROP	18 (7.7)	19 (6.4)	NS
Data are presented as the mean or n (%).			
* chi-square test.			
Abbreviations: NS, not significant; BPD, bronchopulmonary dysplasia; IVH, intraventricular haemorrhage; NEC, necrotizing enterocolitis; LOS, late-onset neonatal sepsis; ROP, retinopathy of prematurity.			

Table 4
Infant Characteristics and Neonatal Outcomes by PDSA Cycles

	PDSA 1 (n = 70)	PDSA 2 (n = 73)	PDSA 3 (n = 152)	<i>P</i>
GA [weeks, $\bar{x} \pm s$]	28.8 $\pm$ 1.6	28.3 $\pm$ 1.7	28.5 $\pm$ 1.7	NS
BW [g, $\bar{x} \pm s$]	1122 $\pm$ 228	1101 $\pm$ 221	1096 $\pm$ 232	NS
Maternal hypertension	29 (41.4)	21 (28.8)	62 (40.8)	NS
Caesarean section	55 (78.6)	45 (61.6)	108 (71.1)	NS
Apgar score at 1 min < 7	30 (42.9)	38 (52.1)	86 (56.6)	NS
Apgar score at 5 min < 7	16 (22.9)	15 (20.5)	38 (25.0)	NS
Hypothermia	49 (70.0)	45 (61.6)	89 (58.6)	NS
Mortality	5 (7.1)	8 (11.0)	13 (8.6)	NS
Pulmonary haemorrhage	6 (8.6)	7 (9.6)	7 (4.6)	NS
BPD	8 (11.4)	5 (6.8)	15 (9.9)	NS
IVH	9 (12.8)	5 (6.8)	24 (15.8)	NS
NEC	3 (4.3)	3 (4.1)	8 (5.3)	NS
LOS	28 (40.0)	21 (28.8)	41 (26.9)	NS
ROP	3 (4.3)	3 (4.1)	13 (8.6)	NS
Data are presented as the mean or n (%).				
Abbreviations: NS, not significant; GA, gestational age; BW, birth weight; BPD, bronchopulmonary dysplasia; IVH, intraventricular haemorrhage; NEC, necrotizing enterocolitis; LOS, late-onset neonatal sepsis; ROP, retinopathy of prematurity.				

Discussion

This is the first prospective, multicentre cohort study to implement QI programs to prevent admission hypothermia in VLBW infants in China. We have succeeded in preventing hypothermia in VLBW infants using standardized targeted temperature bundle management. The use of ambient temperature at 25 °C, polyethylene wrap [21–24], pre-warmed hats [22–24], transport incubator [25], team training and education, temperature documentation and workflow were all relatively easy practice changes but dramatically improved admission temperatures for VLBW newborns. The incidence of admission hypothermia has dropped from 92.3–62% in the post-QI group, with a decrease of 30.3%.

Because hypothermia has been shown to be associated with LOS, IVH, and death [26–30], we monitor survival without serious complications as a secondary outcome. Concomitant with the near elimination of moderate to severe hypothermia has been a trend toward survival improving. The encouraging result is

that our intervention not only prevented hypothermia, but also had a potentially positive impact on the survival rate of VLBW infants.

These reductions may be attributable to the temperature bundle management we implemented, as a significant decline in the first PDSA bundle followed by a gradual decline in each PDSA bundle. In addition to the PDSA bundles, there are no other changes in NICUs, such as neonatal resuscitation process. Similarly, there were no obvious differences between the pre- and post-intervention study populations regarding sex, gestational age, birth weight, caesarean section, antenatal steroids, maternal hypertension, Apgar score at 1 min and 5 min, making changing demographics an unlikely contributor.

Our study confirms previous findings that hypothermia events can be reduced by thermoregulation strategies [11–15, 21]. However, most previous studies have been restricted to the single-center small sample studies. In contrast, our study focused on the limited interventions available in multiple centers, expanding on previous findings. In China, medical staff have poor awareness of the harm of hypothermia in preterm infants during the stabilisation. Our temperature bundle management not only reduces the incidence of hypothermia and improves the prognosis of VLBW infants, but also the bundle is very suitable for China's national conditions and can be generalized. If the bundle could be widely generalized in low - and middle-income countries, more medical staff could be made aware of the harm of hypothermia and take action to improve the outcomes of preterm infants.

However, we should also need to pay attention to the undesired outcomes, such as hyperthermia, which occurred in 1 case after the intervention. One newborn with prolonged time on the chemical mattress had hyperthermic admission temperatures. These cases were rare, and when staff obtained rectal temperature measurements every 30 minutes from delivery room or operating room to admission, they should adjust practice on the basis of the neonate's temperature by removing the chemical mattress when temperatures rose to greater than 37.0 °C.

Prospective data collection, weekly feedback to individual clinicians, and monthly reviews of the percentage of hypothermia cases were key to the overall sustainability of this QI effort. This requires strong nursing support for staff education, real-time feedback to clinicians and nurses in charge, and both nursing and medical leadership support to provide the time for the staff. Our team, even with different experiences in the care of preterm infants (such as pediatric house staff, neonatal nurse practitioners, and neonatologists), implemented successfully a temperature bundle management to prevent hypothermia in premature babies. Moreover, this successful QI initiative experience further supports that we were able to promote the approach in more and more NICUs in China.

The advantage of this study is that it is the first time to recognize that the transition from intrauterine environment to extrauterine environment in preterm infants will lead to hypothermia and affect their prognosis, so as to develop practical and effective programs to reduce the incidence of admission hypothermia. We set up the SNN to collect data prospectively. The SNN is affiliated with China's regional Perinatal Medical Center. If the temperature bundle management can be promoted in China, it will greatly improve the quality of clinical work. By refining the temperature bundle management process, we can

significantly reduce the incidence of hypothermia in VLBW infants. So, the simple and practicable bundle can be extended broadly to more and more NICUs affiliated to perinatal medical centers at all levels in China. Limitations of this study include that this QI initiative took place in level-III NICUs, which is staffed with a large number of pediatric residents and nurses. As a result, PDSA bundles are relatively easy to communicate and issue, while in smaller institutions, it is difficult to implement such bundles rigorously and carefully. Second, although we did not identify any demographic shifts between the pre- and post-intervention periods, there may have been unmeasured differences, such as seasonal room temperature changes, that may have confounded the results. However, the potential value in promoting “NICU forward lead” will likely greatly outweigh the low cost and ease of implementing simple thermoregulation strategies.

Conclusion

We described a successful QI effort to reduce admission hypothermia in VLBW infants in China. The results of this QI initiative indicate that relatively simple targeted interventions can dramatically reduce preventable hypothermia events and potentially improve survival without severe morbidity.

Abbreviations

QI : Quality improvement ; VLBW : Very low-birth weight; NICU : Neonatal intensive care unit; AH : Admission hypothermia; GDM : Gestational diabetes mellitus; GA : Gestational age ; IVH: Intraventricular haemorrhage; NEC : Necrotizing enterocolitis; LOS : Late-onset neonatal sepsis; BPD : Bronchopulmonary dysplasia; ROP : Retinopathy of prematurity.

Declarations

Ethics approval and consent to participate

The Institutional Review Board of Shandong Provincial Hospital Affiliated with Shandong University approved this project (Approval Number: LCYJ: NO. 2019-004). This study has also been registered at the Chinese Clinical Trial Registry (ID: ChiCTR1900020861). All authors have signed written informed consent and approved the submission of this version of the manuscript and take full responsibility for the manuscript. The legal guardian of all participants signed an informed consent form that their data could be used for various clinical studies.

Consent to publish

Not Applicable.

Availability of data and materials

The data that support the findings of this study are available from the corresponding authors upon reasonable request.

Competing interests

The authors declare that they have no conflicts of interest.

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Authors' contributions Y-H Y, doctorate, and professor of medicine, designed the study, trained and supervised the data collectors, interpreted the results and revised the manuscript. L W, the first authors, played a role in the analysis and interpretation of the data and in preparing and drafting the manuscript. Z-J L and F-M L, the co-first authors, designed the data collection instruments, collected data, carried out the initial analyses, and reviewed and revised the manuscript. S-Y B, B L, H-Y X and C-Y Y conceptualized and designed the study, coordinated and supervised data collection, and critically reviewed the manuscript for important intellectual content. All authors have read and approved the manuscript.

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Figures

Figure 1

fishbone diagram. Through investigation and analysis, the possible causes of hypothermia were identified and illustrated in the fishbone diagram. Based on these findings, keeping warm and improve team training and education were identified as key drivers of change.

Figure 2

Flow diagram of the study population.. A total of 636 infants with a BW<1500 g and GA<32 weeks were enrolled in the study on their day of birth; 58 out-born infants were excluded. Additionally, 11 infants with congenital anomalies and/or redirection of intensive care [limited care (not intensifying medical treatment) or withdrawal of care], 10 infants with maternal pyrexia and 27 infants with missing data were excluded. The remaining 530 infants were included in this analysis.

Figure 3

P-chart of the hypothermic birth rate with control limits. The new thermoregulation protocol was introduced into practice in January 2019. The incidence of AH decreased dramatically in the post-QI group, with a reduction from 92.3% to 62% ($p < 0.001$). The mean admission temperature had also significantly increased to $36.0 \pm 0.7^{\circ}\text{C}$ from $35.5 \pm 0.7^{\circ}\text{C}$ ($P < 0.001$). The rate of AH was tracked by the control chart.

Supplementary Files

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