“Golden Hour” quality improvement intervention and short-term outcome among preterm infants

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Abstract

Objective To evaluate the impact of a quality improvement intervention during the first hour of life (“Golden Hour”) on short-term preterm neonatal outcome.

Study design A comprehensive protocol designed for initial stabilization and treatment of preterm infants that included cord blood sampling, use of a dedicated resuscitation room and improved team communication using Crew Resource Management tools. The infants admitted before and after implementation of the protocol were retrospectively compared in a matched case-control design.

Results There were 194 infants in the intervention group and 194 controls. Admission temperatures improved significantly from a mean of 35.26 °C to 36.26 °C ($P < 0.001$), and late-onset sepsis and bronchopulmonary dysplasia rates lowered significantly ($P = 0.035$ and $P = 0.028$, respectively) in the intervention group. There was trend towards reduction in early blood transfusion and ventilation duration.

Conclusions A “Golden Hour” quality improvement intervention was of significant benefit for preterm neonates. Further follow-up to assess long-term effects is warranted.

Introduction

The “Golden Hour” concept is based on the assumption that care of patients in the first hour of life is of critical importance to patient outcome. This concept had emerged primarily in the setting of emergency medicine, but it is now being increasingly applied in the field of neonatology [1–4]. Preterm infants have immature adaptive systems, including poor thermal control [5], surfactant deficiency, and poor respiratory drive. These fundamental issues need to be addressed by the neonatologist in a setting of resuscitation that tends to be susceptible to error and miscommunication

The importance of the initial treatment of these infants has been demonstrated in several studies [6, 7].

The effect of thermoregulation on outcome is a prominent example. Hypothermia is defined by the World Health Organization as a temperature below 36.5 °C, although an axillary measurement of 36 °C and over is considered acceptable at admission to the neonatal intensive care unit (NICU) [8, 9]. Hypothermia has been shown to impair lung function and surfactant production [10–12], as well as negatively impact the immune and other organ systems [13–16]. Several studies have linked hypothermia at NICU admission to increased risk of infection, intraventricular hemorrhage (IVH) and death [17, 18]. The landmark study by Laptook et al. in 2007 [19] showed a 28% increase in mortality and an 11% increase in late-onset sepsis for every 1 °C drop below 36 °C at admission.

Another important example is respiratory support during resuscitation, where use of positive-end-expiratory-pressure (PEEP) with minimal supplemental oxygen to achieve targeted saturations was shown to improve outcome and is now the accepted standard of care [20–22]. Studies have also shown the importance of team briefing, communication and collaboration during resuscitation and their impact on

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patient outcome [23]. These measures can also be improved by using a standard treatment protocol along with training and simulation [24–26].

In light of the evidence, based on accumulating literature for the importance of the care given in the first hours of a premature infant's life, we examined the current status in our hospital as follows: we have looked at admission temperature in the last 3 years and found that admission temperature below 36 °C was observed in 59.1, 64.3, 59.7, 53.1% infants in the years 2011–2014 respectively. Our aim was to have 100% of the infants with admission temperature above 36 °C.

We have observed resuscitations that were done in the delivery rooms or operating rooms. We found that there were significant variations and inconsistency in the initial care provided by our NICU staff. The reassociation area in each room was not warm as recommended, no use of hats or plastic bags on regular basis, there were no available T-piece for adequate ventilation in every work-station, equipment was lacking and was not organized. Communication between the staff was lacking and not clear. We identified several areas for improvement and hypothesized that improvement and standardization of care by implementing a “Golden Hour” protocol will improve a number of parameters, primarily admission temperatures, and possibly improve outcome.

The aim of this study was to evaluate the impact of the “Golden Hour” quality improvement intervention on short-term neonatal outcome.

Methods

On September 1, 2015, a comprehensive protocol was implemented for the admission of preterm infants of gestational age (GA) $\leq 32 + 6$ weeks who were born at the Sheba Medical Center, a tertiary medical center in Israel that has approximately 10,000 deliveries per year. The protocol included preparation, initial stabilization, and treatment after birth. Development of the protocol included a review of the literature, composition of clinical care pathways, checklists and guidelines based on the current literature and peer review of these guidelines.

All the following measures were practiced in dedicated simulations before starting the project, and were rolled out within a week of protocol initiation. The areas covered by the protocol are as follows:

A dedicated resuscitation room was designed and built in the delivery ward and operating rooms. This provides optimal conditions for advanced resuscitation and supportive care as well as tools for resuscitation review and quality control.

Simulations with full team participation (including midwives and obstetricians) were performed for the introduction and assimilation of the protocols and for orientation in the resuscitation room. This was done in collaboration with the National Center for Medical Simulation, based in Sheba Medical Center.

Standardized communication techniques using Crew Resource Management (CRM) tools were initiated. Non-participating observers, including doctors and nurses, assessed team performance and communication as well as other subjective parameters.

Preparation for admission began with a briefing of the team before NICU admission and the delegation of roles by a selected team leader. The team uses a detailed checklist (Appendix 1) to ensure the availability of all necessary equipment for advanced resuscitation as well as the readiness of the resuscitation area.

For thermoregulation, ambient temperatures are maintained within an accepted range (23 °C in the operating rooms, 25–27 °C in the delivery rooms and resuscitation room). During resuscitation, thermoregulation is maintained by means of polyethylene bags, caps and prewarmed sheets and blankets. Transport of infants is done in a prewarmed portable incubator.

Respiratory support includes positive pressure ventilation with adequate PEEP, and limited peak inspiratory pressure is given when needed via a T-piece resuscitator (“Neo-puff”), avoiding the use of self-inflating bags. In accordance with Neonatal Resuscitation Guidelines [19], supplemental oxygen is given judiciously while targeting expected preductal saturations and avoiding hyperoxia during resuscitation as well as during transport to the NICU.

The volume of infant blood sampling on admission is reduced by using cord blood sampling for cultures, complete blood count (CBC), coagulation factors and additional tests as indicated. The reason for including cord blood sampling in this protocol was an attempt to reduce the volume of blood taken from the infant on admission.

On arrival to the NICU, the infant is admitted and examined within several minutes, and intravenous access is obtained quickly to allow parenteral nutrition and antibiotics to be given within 1 h of birth. Surfactant is administered according to accepted guidelines as soon as possible, no later than 2 h from admission.

The admission parameters and short-term outcome of all preterm infants of GA $\leq 32 + 6$ weeks that were admitted under the Golden Hour protocol in the 18-month study period were recorded. Infants with major congenital malformations were excluded. The recorded data included GA, birth weight (BW), single or multiple gestation, appropriate-, small- or large-for-gestational age (SGA/AGA/LGA), gender, antenatal steroids, temperature on admission, first

Table 1 Patient demographics and results

Variables	Cases (n = 194)	Controls (n = 194)	P value
Gestational age (range)	30.19 (24–32.6)	30.19 (24.2–32.6)	0.834
Birth weight	1325.8 (380–2538)	1334 (500–2177)	0.478
SGA	19.6% (38/194)	19.1% (37/194)	1
ANS	90.7% (176/194)	88.6% (172/194)	0.617
Admission temperature	36.26	35.26	<0.001
First blood glucose < 40	35.1% (68/194)	25.8% (50/194)	0.047
First 72 h PCI	10.3% (20/194)	16.5% (32/194)	0.065
Mechanical ventilation	36% (71/194)	42% (82/194)	0.228
Ventilation days (range)	6 (1–28)	8.07 (1–69)	0.097
BPD ^a	5.9% (11/188)	12.4% (23/186)	0.028
Postnatal steroid treatment	3.2% (6/190)	5.3% (10/192)	0.424
Late-onset sepsis	10.4% (20/193)	17.7% (34/192)	0.035
NEC ^a	3.7% (7/189)	3.7% (7/188)	1
IVH I–II	14.5 (28/193)	11.9 (23/193)	0.471
IVH III–IV	4.2% (8/193)	4.7% (9/193)	1
PVL ^a	5.4% (10/184)	4.8% (9/187)	0.815
Death	3.6% (7/194)	4.6% (9/194)	0.774

Data are presented as mean (range) or percent (n/N).

P value is based on paired sample *t* test for continuous variables or McNemara test for dichotomous variables

GA gestational age, BW birth weight, SGA small for gestational age, ANS antenatal steroids, DS dextrose stick, PCI packed cells infusion, BPD bronchopulmonary dysplasia, NEC necrotizing enterocolitis, IVH intraventricular hemorrhage, PVL periventricular leukomalacia

^a We have removed the infants that died before the outcome could be measured—such as BPD, PVL, or NEC

blood sugar level, blood transfusion in the first 72 h, respiratory distress syndrome, mechanical ventilation, bronchopulmonary dysplasia (BPD—defined as oxygen at 36w PMA) and postnatal steroid treatment, late-onset sepsis, IVH, periventricular leukomalacia (PVL), necrotizing enterocolitis (NEC—defined as proven NEC, Bell's stage 2 and up) and death.

Each infant in the study group was matched to a control infant born with similar demographics, i.e., GA, BW and singleton vs. multiple gestation, during the 2 years prior to implementation of the Golden Hour protocol. A control period of 2 years was used to enable appropriate matching for all demographic. Blinded matching with controls was done for all processes and outcome parameters that were compared in this study. The study was approved by the Sheba Medical Center ethics (Helsinki) committee. Informed consent was waived.

Statistical analysis

Based on the results of previous studies (referenced in the introduction section), we estimated that a sample size of approximately 200 in each study group would yield a power of at least 90% to detect a 20–25% reduction in risk for the major outcome parameters. The comparison between the study and control groups was done using the paired sample *t* test for continuous variables or the McNemara test for dichotomous variables. A *P* value of ≤ 0.05 was considered to be statistically significant. Analyses were performed using IBM SPSS statistics software version 22.

Results

During the 18-month study period, 248 preterm infants of GA 24–32 + 6 weeks were born at the Sheba Medical Center. Excluded were 3 who had major congenital malformations, 51 who were not being treated in the dedicated resuscitation area and so did not benefit from all the measures included in the protocol. These are singleton preterm infants that were born spontaneously in the delivery room and not in the OR—where a similar resuscitation area was built only later, towards the end of the study period.

The remaining 194 infants comprised the study group.

The characteristics of the study infants and their matched controls are listed in Table 1. Admission temperatures improved significantly after protocol initiation (Fig. 1). The rate of late-onset sepsis for the study group decreased significantly during the study period compared to the controls ($P = 0.035$), as did the rate of BPD ($P = 0.028$). The rate of hypoglycemia (glucose < 40 mg/dl) in the first measured blood glucose was higher in the study group ($P = 0.047$). The need for a red blood cell (RBC) transfusion in the first 72 h of life decreased, but the difference did not reach a level of significance ($P = 0.065$). The need for mechanical ventilation did not change significantly, but a trend was observed towards decrease in the duration of ventilation for the study group. The rates of other adverse outcomes, including NEC, IVH, PVL and death, were not significantly different between the study and control groups.

We then collected the data for infants born ≤ 28 weeks ($n = 49$, Table 2) and compared them with matched controls. Admission temperatures were again significantly improved in the study group, rising from 34.93 °C to 36.25 °C ($P < 0.001$). The rate of late-onset sepsis decreased even more significantly in the study group compared to the control group ($P = 0.008$). This subgroup analysis also revealed a strong trend towards a decrease in the need for ventilation ($P = 0.067$), but the decrease in the rate of BPD did not reach statistical significance ($P = 0.055$). There was no significant difference between these two subgroups in the

Fig. 1 Admission temperature improvement after protocol initiation. Comparison of temperature admission of infants born before intervention (35.26 °C), protocol initiation starts on September 1st (green line). Improvement of admission temperature to 36.26 °C ($P < 0.001$)

Table 2 Results for preterm infants 28 weeks and under

Variables	Cases <i>n</i> = 49	Controls <i>n</i> = 49	<i>P</i> value
Admission temperature	36.25	34.93	<0.001
First blood glucose <40	28.6% (14/49)	16.3%(8/49)	0.151
First 72 h PCI	34.7% (17/49)	36.7% (18/49)	0.833
Mechanical ventilation	65.3% (32/49)	81.6% (40/49)	0.067
Ventilation days (range)	9.3 (1–28)	15.6 (1–69)	0.101
BPD ^a	14 % (6/43)	31.1% (14/45)	0.055
Postnatal steroid treatment	6.7% (3/45)	14.6 % (7/48)	0.218
Late-onset sepsis	22.9% (11/48)	49% (24/49)	0.008
NEC ^a	9.1% (4/44)	13% (6/46)	0.551
IVH I–II	27.1% (13/48)	20.4% (10/49)	0.44
IVH III–IV	14.6% (7/48)	18.4% (9/49)	0.616
PVL ^a	10% (4/40)	11.1% (5/45)	0.868
Death	14.3% (7/49)	8.2% (4/49)	0.337

Data are presented as mean (range) or percent (*n*/*N*). *P* value is based on paired sample *t* test for continuous variables or McNemara test for dichotomous variables

GA gestational age, BW birth weight, SGA small for gestational age, ANS antenatal steroids, DS dextrose stick, PCI packed cells infusion, BPD bronchopulmonary dysplasia, NEC necrotizing enterocolitis, IVH intraventricular hemorrhage, PVL periventricular leukomalacia

^a We have removed the infants that died before the outcome could be measured—such as BPD, PVL, or NEC

rates of early blood transfusion, hypoglycemia or other adverse outcomes, including NEC, IVH, PVL, and death.

Discussion

This study shows a significant improvement in admission temperatures along with a reduced rate of late-onset sepsis and BPD after implementation of a “Golden Hour” quality improvement intervention in an NICU. The study also shows a trend towards a decrease in the need for early RBC transfusion as well as a trend towards a decrease in the duration of ventilation, but the reduction in the risk for BPD and LOS are the most striking findings, and this is most probably due to the reduction of hypothermia.

An infant’s risk of mortality is at its highest immediately after birth, with 25–45% of neonatal mortality occurring during the first 24 h of life and 75% during the first week of life. With prematurity and asphyxia being main causes of early mortality, interventions addressing initial care including thermoregulation and resuscitation could have a substantial impact on neonatal mortality prevention [27]. The negative effect of hypothermia on lung function and acid-base balance, and thus the worsening of respiratory disease, has been previously described [10–12]. The current

results support those reports by showing a significant decrease in the duration of mechanical ventilation as well as the lower risk for BPD in the study group and similarly in a subgroup of infants 28 weeks and under. This is also the most likely explanation for the connection between hypothermia and late-onset sepsis, since prolonged ventilation raises the risk for infection both directly via ventilator-associated infections and by delaying full enteral feeding and thereby prolonging the need for indwelling catheters [13]. Another possible explanation for the link between hypothermia and sepsis is direct damage by hypothermia to the immune system, mainly innate immunity, adversely affecting the function of phagocytes and the production of cytokines and thus increasing the susceptibility of the infant to bacterial infection [14–16], although this mechanism would more likely increase the risk for early- rather than late-onset sepsis as observed in the current study. Numerous studies have shown an association between hypothermia on NICU admission and late-onset sepsis [17–19], and our findings are in agreement.

We observed a strong trend towards a decrease in the need for early blood transfusion. This finding could be explained by the use of cord blood for the initial lab tests as part of the Golden Hour protocol, thus reducing the volume of infant blood sampling on admission. This is especially important in extremely LBW infants, when the volume of blood taken for routine tests, such as CBC and cultures, is more significant in proportion to the infants’ total blood volume. The lack of a more significant difference in the subgroup analysis of infants 28 weeks and under could be due to the small sample size.

The finding of a significant increase in the rate of hypoglycemia in the study group compared to controls is contrary to those of previous studies [18] that linked hypothermia to an increased risk for hypoglycemia. We speculate that the hypothermia and worse respiratory disease lead to increased stress and thus reduce the risk for hypoglycemia.

CRM practices, which were originally designed to reduce human error and improve safety in aviation [28], have also been shown to improve efficiency and communication and improve safety in medical scenarios [29, 30]. These practices, along with simulation training, have been shown to have a positive effect on patient outcome as well [22–24, 31].

The NICU staff’s collaboration and simulation training with the delivery room staff shifted them from the position of observers to that of active participants in the resuscitation procedures. This shift along with CRM practices was felt by the participants to be highly instrumental in the improvement of process parameters in the study period. Unfortunately, the lack of data from the period preceding the

protocol implementation precludes objective evaluation and analysis.

There is, of course, no single parameter of initial care that can be said to be of more importance than others, and it is nearly impossible to isolate the effect of each aspect of treatment on the outcome of the patient. This quality improvement intervention has therefore been designed to address and standardize all aspects of care both individually and in combination. The overall effect of quality improvement initiatives regarding initial care in the first “Golden Hour” has been shown in previous studies, demonstrating improvement in admission temperatures and other process parameters [32–34] as well as decreased morbidity and mortality [35].

This study had some limitations. Its retrospective design may have enabled selection and information biases, and the longer control period used for proper matching is another possible source of bias. Another possible limitation is the presence of another intervention to improve outcome during the study period. The “Chasing zero”: an initiative started in April 2014, this is a national initiative designed to reduce the rate of late-onset sepsis in preterm infants in Israel; however, it was implemented few months preceding the control period of the study and therefore should not weaken the results.

After the initiation of this project and evaluate its improvement in the parameters mentioned above, another resuscitation room was built in the delivery rooms. A closed loop camera was placed in the resuscitation rooms so that the overview of each resuscitation is available.

By implementing quality improvement protocols and guidelines, it is possible to improve the care of preterm infants. We currently target the extremely low birth weight premature infants in order to improve their resuscitation with minimal handling protocols during the first days of life, especially focusing on steps to reduce IVH and improve neurodevelopmental outcome.

In conclusion, the implementation of a “Golden Hour” quality improvement intervention seems to enhance the quality of initial care in an NICU, leading to improvement in admission temperatures, and therefore improving patient outcome by decreasing BPD and late-onset sepsis rates. Its effect on the long-term outcome of these infants warrants investigation. Quality improvement initiation should be encouraged in order to advance our treatment in preterm infants, improving short- and long-term outcome.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflicts of interest.

Ethics approval The study protocol conforms with all ethical guidelines and has been approved by the institute's committee on human research. Informed consent is not applicable in this study.

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