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Could a neonatal care bundle be a promising strategy for the prevention of intraventricular hemorrhage in preterm infants? A retrospective cohort study

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ABSTRACT

Background. Germinal matrix-intraventricular hemorrhage (GM-IVH) remains a major cause of morbidity and mortality in preterm infants, particularly in the first days of life.

Objectives. The aim of this study was to describe the results of introducing the Neonatal Care Bundle (NCB) in the first 72 hours of life on the incidence of GM-IVH in preterm infants.

Methods. A retrospective-observational cohort study of preterm infants with a gestational age <30 weeks and with birthweight <1500 g, before and after the implementation of the protocol, with historical control was conducted. The infants were divided into two groups. Group 1 included infants that received standard neonatal care, and Group 2 included infants that received the NCB. The NCB protocol includes keeping the infant in the midline head position, elevating the head of the incubator to 30°, and avoiding a head lowering position, sudden raising of the legs, or sudden position changes for the first 72 hours.

Results. In total, 186 preterm infants were enrolled. The frequency of any grade of GM-IVH and severe IVH were statistically significantly lower in NCB group ($p < 0.05$). In the subgroup analyses of the patients according to birth weight, the rate of GM-IVH was seen to decrease from 41% to 24% in preterm infants <1000 g after NCB.

Conclusion. This study adds to the limited literature suggesting that rates of GM-IVH may decrease with increased awareness, standardization, and careful neonatal care during the first 72 hours, the period when preterm infants are at the highest risk.

Keywords: *patient care bundles; cerebral intraventricular hemorrhage; neonate; infant, premature.*

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INTRODUCTION

Germinal matrix-intraventricular hemorrhage (GM-IVH) is a serious complication, especially in preterm births and is the most common cause of cerebral damage seen in preterm.[1] Despite the advances and developments in perinatal care and neonatology in recent years, it continues to be a major problem with a deleterious effect on neurological development and mortality.[2,3] As demonstrated in the current literature, the incidence of GM-IVH increases with declining gestational age. It is most diagnosed in preterm born less than 32 weeks and with a birth weight below 1500 grams. Current literature reports an incidence of 20-25%.[4] In the cohort of extremely preterm born at less than 26 weeks, the prevalence of GM-IVH has been reported to be approximately 45%.[5] Despite numerous quality improvement initiatives, data on the incidence of severe IVH from other regions shows that the rate across Canada has remained unchanged over the five-year period from 2013-2017. This rate is 20-22% in infants aged 22-25 weeks and 7-10% in infants aged 26-28 weeks.[6]

The most common causes of GM-IVH include alterations in cerebral blood flow, a deficient extravascular matrix, and fragility of the immature cerebral germinal matrix vessels in preterm infants.[7] Fluctuations in cerebral blood flow caused by disruptions and impairment in autoregulation, especially in very premature infants, lead to an increase in cerebral venous flow and GM-IVH.[8] Consequently, the occurrence of GM-IVH can be avoided by implementing meticulous procedures and interventions within the initial 72-hour period, along with the mitigation of alterations in cerebral blood flow. The aim of this study was to describe the results of introducing the Neonatal Care Bundle (NCB) in the first 72 hours of life on the incidence of GM-IVH in preterm infants.

MATERIALS AND METHODS

Approval for this retrospective-single center study, conducted in a university hospital between January 2020-December 2021, was approved by the Ethics Committee (2011-KAEK-252022/06-09). The study cohort comprised preterm infants born <30 weeks and with birthweight <1500 g, who were admitted to the Neonatal Intensive Care Unit (NICU). Standard, routine nursing care was provided in our unit in 2020. Patients were positioned in various positions without paying attention to the position of the head. Tilting the incubator was not part of routine care and during diaper change the legs were often suddenly lifted. In 2021, nursing care was provided by nurses who received 3-day NCB bundle training. The NCB protocol includes keeping the head of the infant in the midline head position, elevating the head of the incubator to 30°, and avoiding a head lowering position, sudden raising of the legs, or sudden

Table 1. Key driver diagram of Neonatal Care Bundle

AIM	PRIMARY DRIVER	SECONDARY DRIVER	POTENTIAL INTERVENTION
Reduce rate of intraventricular hemorrhage and severe intraventricular hemorrhage in extremely preterm infants.	Prevention of fluctuations in cerebral blood flow.	Education of neonatal nurses. Monitorization of adherence by supervising nurse.	Neonatal Care Bundle (NCB) for the first 72 hours. 1. Keeping the head of the infant in the midline position. 2. Elevating the head of the incubator to 30º. 3. Avoiding a head lowering position. 4. Avoiding sudden raising of the legs. 5. Avoiding sudden position changes.

position changes for the first 72 hours (*Table 1*). Adherence to the protocol was observed by a supervising nurse, but was not formally quantified; therefore, adherence was assumed rather than objectively measured. The NCB protocol was limited to nursing care, but all the NICU staff was instructed as well. Preventive measures of GMH-IVH such as careful management of ventilatory settings or hemodynamic stabilization are routinely applied by other members of the NICU team. The infants included in the study were divided in two groups. Group 1 included that received standard care, Group 2 included that received the NCB care. For the IVH analysis, an alpha value of 0.05 and a beta value of 80% were aimed and showed that the number of patients to be included in both arms was adequate. The study exclusion criteria were defined as the presence of major congenital and central nervous system abnormalities, chromosomal abnormalities, and infants born in other centres.

All patients were evaluated according to the preterm ultrasonographic monitoring protocol defined by the same 2 neonatologists with same devices for both periods.[9] Since our study was a retrospective study, ultrasound images were analysed blindly by the same 2 specialists without considering the change in nursing care. Cranial ultrasound scanning(cUS) was performed on all patients for the first time in the first 24 hours and for the second time at 72 hours of age, and then weekly cUS follow-up was performed.[9] Classification of GM-IVH was made as described by Volpe.[2,9] The definition of IVH requiring treatment is the implementation of neurosurgical intervention (such as ventricular drainage, ventriculo-subgaleal shunt, ventricular access) in preterms progressing to hydrocephalus due to severe IVH.[10] The presence of GMH-IVH and the classification of the images were verified by an external specialist.

Statistical analysis

Study data were analysed statistically using SPSS version 22.0 (SPSS Inc, Chicago, IL, USA). Continuous variables were presented as median (minimum-maximum) or mean (standard deviation), according to the normality of the distribution, and categorical values were presented as numbers and percentages. Chi-square analysis or Fisher's exact test was used for comparisons of categorical variables, the Mann-WhitneyU test and Kruskal-Walli's test were used for comparisons of non-parametric variables. Factors with a significant effect on IVH based on prior knowledge were identified using logistic regression analysis. Results were presented as odds ratios (OR) and 95% confidence interval (CI), and the level of statistical significance was set at $p < 0.05$.

RESULTS

Of the 20 920 live births during the defined study time, a total of 1407 premature infants were admitted to the NICU. After implementation of the study exclusion criteria, 186 patient files were included in the final assessment; 105 infants in Group 1 who were administered standard care, and 81 infants in Group 2 who were administered the NCB intervention. A comprehensive flowchart delineating the study population is presented in *Figure 1*, while the demographic characteristics of the study population are shown in *Table 2*. There was no statistically significant difference between groups ($p > 0.05$). In the comparisons of clinical outcomes between the groups, bronchopulmonary dysplasia was determined at a statistically significantly higher rate in Group 1 ($p < 0.05$) (*Table 3).*

A subsequent analysis of the outcomes of the groups revealed a statistically significant decrease in the incidence of any grade of GM-IVH in Group 2 compared to Group 1 ($p < 0.05$). The incidence of severe IVH and IVH requiring treatment was found to be statistically significantly lower in Group 2 ($p < 0.05$). The mortality rate was lower in Group 2 but not at level of statistical significance. Neurological outcomes parameters are shown in *Table 4*. In the subgroup analyses of the infants according to birth weight, the rate of GM-IVH was seen to decrease from 41% to 24% in preterm infants <1000 g after NCB. The rate of GM-IVH in preterm infants between 1000-1500 g was seen to decrease from 25% to 21% after NCB.

Logistic regression analysis was conducted to determine the association of the NCB on any grade IVH when adjusted for GA, birthweight, 5-min Apgar score, antenatal steroid use, and mode of delivery (adjusted odds ratio (OR): 0.510; 95% confidence interval (CI): 0.265–0.983; $p = 0.04$). Some potentially relevant confounders, such as chorioamnionitis, antibiotic use, and PDA, were not adjusted due to the inadequate sample size. The logistic regression analysis results also showed the association with lower severe IVH rates (adjusted OR: 0.368; 95% CI: 0.138–0.984; $p = 0.04$) (*Table 5*).

Figure 1. Flowchart of the study

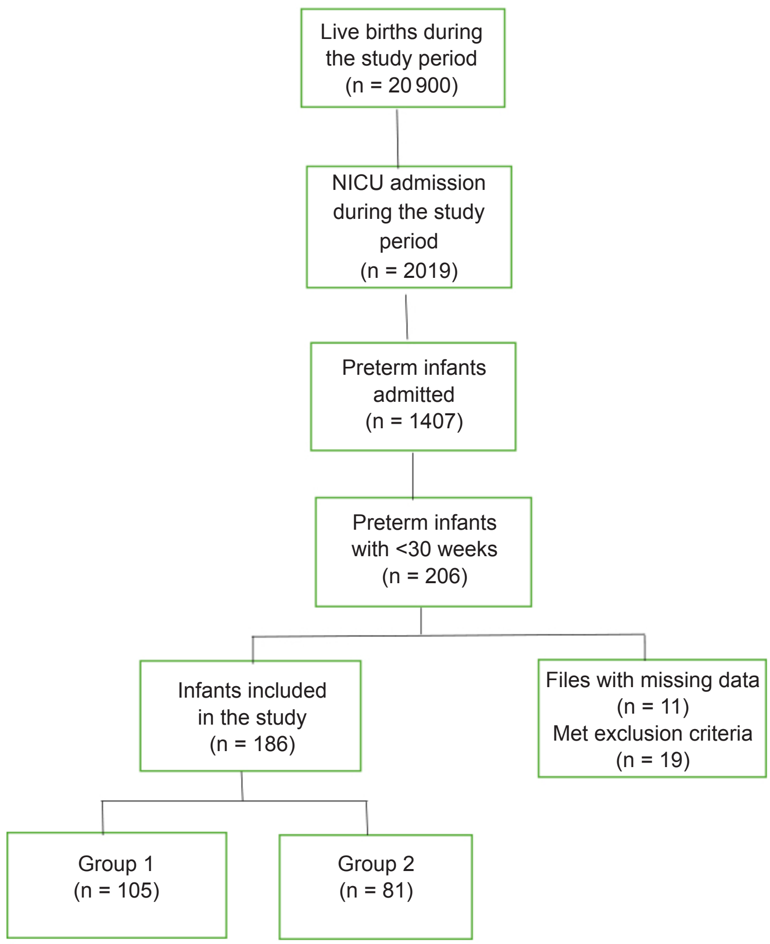

Table 2. Neonatal and maternal characteristics of the study groups

	Group 1 (n = 105)	Group 2 (n = 81)	*p*
Gestational age, week median (IQR)	26 (24-28)	27 (25-29)	0.10[a]
Birth weight, g median (IQR)	860 (650-1045)	860 (695-1390)	0.20[a]
Sex, n (%)			
Male	57 (54)	38 (47)	0.30[b]
Caesarean section, n (%)	84 (80)	64 (79)	0.80[b]
Apgar score, median (IQR)			
Minute 1	5 (3-7)	5 (4-7)	0.06[a]
Minute 5	7 (5-8)	7 (6-9)	0.07[a]
Antenatal steroids, n (%)			0.90[a]
No	46 (44)	34 (42)	
Single course	8 (8)	7 (9)	
Repeated course	51 (48)	40 (49)	
Preeclampsia, n (%)	23 (22)	13 (16)	0.30[b]
Chorioamnionitis, n (%)	11 (11)	16 (20)	0.08[b]
Multiparity, n (%)	10 (10)	13 (16)	0.20[b]
Intrauterine growth retardation, n (%)	9 (9)	10 (12)	0.60[b]
Antenatal Mg sulphate administration, n (%)	67 (64)	56 (70)	0.70[b]
Delay cord clamping, n (%)	65 (62)	52 (64)	0.90[b]

[a] *Mann-Whitney U test,* [b] *Chi-square test.*

Table 3. Clinical findings of the groups

	Group 1 (n = 105)	Group 2 (n = 81)	*p*
Respiratory distress syndrome, n (%)	90 (86)	70 (86)	0.80[a]
Intubation at the delivery room, n (%)	65 (62)	56 (69)	0.30[a]
Intubation in the first 72 hours, n (%)	79 (75)	62 (77)	0.80[a]
Intubation time in the first 72 hours (hours), median (IQR)	60 (2-72)	60 (10-72)	0.80[b]
Minimally invasive surfactant, n (%)	12 (11)	13 (16)	0.30[a]
Extubating in first 72 hours, n (%)	10 (10)	11 (14)	0.30[a]
Pneumothorax, n (%)	7 (4)	5 (3)	0.90[a]
Inotropic support in the first 72 hours, n (%)	10 (10)	11 (14)	0.40[a]
Need for fresh frozen plasma, n (%)	22 (21)	25 (31)	0.10[a]
Patent ductus arteriosus, n (%)	54 (51)	37 (46)	0.40[a]
Sepsis, n (%)	28 (26)	23 (28)	0.70[a]
Necrotizing enterocolitis, n (%)	7 (7)	4 (5)	0.70[c]
Bronchopulmonary dysplasia, n (%)	34 (32)	13 (16)	0.01[a]
Retinopathy of prematurity requiring treatment, n (%)	14 (13)	5 (6)	0.10[a]

[a] Chi square test, [b] Mann-Whitney U test.

Table 4. Neurological outcomes and mortality

	Group 1 (n = 105)	Group 2 (n = 81)	*p*
IVH (any phase), n (%)	40 (38)	19 (24)	**0.03**[a]
Cystic PVL, n (%)	6 (6)	4 (5)	1.00[b]
Severe IVH, n (%)	19 (18)	6 (7)	**0.03**[a]
IVH requiring intervention, n (%)	11 (11)	2 (3)	**0.03**[a]
PVHI, n (%)	9 (9)	3 (4)	0.20[a]
Seizure, n (%)	11 (11)	6 (7)	0.40[a]
Death, n (%)	29 (28)	18 (22)	0.40[a]

[a] Pearson Chi-square test test, [b] Fisher's Chi square test.
IVH: intraventricular hemorrhage; pvl: periventricular leukomalacia; pvhi: periventricular hemorrhagic infarct.

Table 5. Association of Neonatal Care Bundle with intraventricular hemorrhage (logistic regression model)

	Group 1 (n = 105)		Group 2 (n = 81)		aOR (95% CI)	*p*
	n	%	n	%		
Any IVH	40	38,1%	19	23,5%	0.510 (0.265-0.983)	**0.04**
Severe IVH	19	18,1%	6	7,4%	0.368 (0.138-0.984)	**0.04**

IVH: intraventricular hemorrhage.
Model adjusted for GA, birthweight, 5-min Apgar score, antenatal steroid use, and mode of delivery.

DISCUSSION

Premature infants are highly at risk of GM-IVH due to the immaturity of their innate immune system, and GM-IVH has an increased risk of morbidity and mortality.[11,12] This condition occurring in the first days of life both decreases the chance of survival and can cause lifelong permanent damage.[12] In this study, there was a significant decrease in the rates of any-grade GM-IVH and severe GM-IVH after NCB training given to nurses in NICU compared to the rates seen in preterm infants before training. This study contributes to the neonatal literature as one of the few reports suggesting that NCB may help reduce GM-IVH.

The germinal matrix is a transient fetal brain structure that produces specific neurons and glial cells and regresses almost completely by 36 weeks of gestation.[13,14] Because of its immaturity and vascular fragility, venous congestion and increased cerebral venous pressure can easily lead to GM-IVH.[2,15] Therefore, the risk is particularly high in infants born before 30 weeks.[16] GM-IVH typically occurs in the first few days of life, most often within 24 hours, and may progress between days 3 and 5.

In the present study, all preterm infants born at <30 weeks who were at risk of GM-IVH were included. Cranial ultrasound was performed within the first 24 hours, repeated at 72 hours, and then weekly during hospitalization. This approach allowed us to capture both early and evolving hemorrhages.

Sudden fluctuations in cerebral blood flow can cause GM-IVH. The regulation of cerebral blood perfusion and blood flow in preterm infants is more immature than in term neonates, and this leads to "pressure passive" circulation because cerebral blood flow cannot be protected during blood pressure fluctuations, ultimately damaging fragile vessels. In a previous study of infants weighing <1000 g, the infants were positioning flat supine or in a 30º elevated position. The results of that study showed that head elevation position of 30º with the head maintained in the midline is safe and beneficial in terms of lower FiO_2 requirements, improved mean blood pressure, and potentially improved survival.[17] In another study, it was speculated that a non-physiological fixed supine position for prolonged periods in infants resulted in agitation, and this could be associated with hemodynamic changes causing severe IVH.[18] However, there are also studies showing that this does not alter blood flow or the incidence of IVH.[19,20] In the presented study, it was hypothesized that a significant effect would be seen by preventing an increase in intracranial blood circulation with elevation of 30°.

The results of the NCB in certain studies have shown variation according to GA. In one study, a significant decrease was observed in severe brain injury and mortality rates, particularly in infants <27 weeks.[21] However, a following study demonstrated the effect and favorable outcomes of an evidence-based neuroprotection care on long-term neurodevelopmental impairment (NDI) in extremely premature infants.[22] In a further study conducted with NIRS on older infants, position-related hemodynamic changes were only observed in the subgroup of infants born less than 26 weeks gestational age.[23,24]

A study found that implementing a bundle of evidence-based, potentially better practices using specific electronic order sets was associated with a lower rate of severe IVH or death in the first week among extremely preterm infants. They objectively assessed the effect of bundles using quality improvement methodology and demonstrated that the rate of severe IVH or death in the first week after birth decreased from the baseline rate of 27.4% to 15.0%.[25] In the present study, a decline in the incidence of GM-IVH was observed, from 41% to 24%, in preterm infants with a birth weight of <1000 g, following NCB implementation. It is crucial to have this substantial decrease, especially in preterm infants with birth weights of <1000 g, who are most predisposed to GM-IVH. In our study, although there was a significant difference in the rate of severe hemorrhage between the groups, there was no difference in mortality rate, possibly because IVH was not the only factor influencing mortality in very preterm infants, and our sample size was relatively small.

In addition to many studies related to elevated head positioning, there are also reports in the literature regarding head left/right rotation or head-tilting in premature infants. These studies have indicated that head-rotation or head-tilting has no significant effect on cerebral oxygenation in preterm infants.[22,26] In a review of cerebral hemodynamics, it was emphasized that no effect was seen on cerebral hemodynamics after the head turning and/or lowering position. However, most of the preterm infants evaluated were older than 1 week and had thus passed the period of greatest risk for GM-IVH.[27] It has been demonstrated that both staff education, accurate implementation in the golden hour and awareness of interventions reduce the rates of severe hemorrhage in preterms.[28,29] In this study, midline positioning was evaluated, and right/left rotation, which can alter the flow of blood, was avoided.

Adherence to the bundle is critical for its effectiveness. In our study, adherence was assumed rather than objectively measured, which represents a limitation of our findings. Previous studies have shown that improvements in adherence are associated with significant reductions in severe IVH rates. They demonstrated that the rate of adherence to the bundle improved from 24% to 88%, and the incidence of severe IVH decreased from 9.8% to 2.4%, a reduction of 76% from baseline.[30] The quality improvement (QI) methodology is the most appropriate for objectively assessing the effect of the implementation of packages of measures or bundles.[25-30] Improvements that are made in the NICU, such as staff training and appropriate resource utilization, affect bundle applicability. However, staff compliance and differences in NICU environments could potentially effect efficacy.

Nevertheless, this study has some limitations that should be mentioned. First, it was a retrospective, single-center study. As the study was conducted in a single center, the results cannot be extrapolated to other units or countries but can provide ideas for new studies and practical applications. The second limitation is unmeasured adherence and the inability to establish causality. There may have been innovations in neonatology in different years, although there was no difference in the treatment protocol in our unit, and there were no statistically significant and known changes in the nurse-to-patient ratio and the nurse-patient profile. Because adherence was monitored informally and not objectively quantified, fidelity to the intervention remains uncertain. Future studies should include objective adherence audits to strengthen validity. Third, in our study, we recorded the highest grade of hemorrhage in the first 72 hours, and we did not specifically identify cases of increased hemorrhage. Some potentially relevant confounders, such as chorioamnionitis, antibiotic use, and PDA, were not adjusted for in the logistic regression model because there were no statistically significant differences in these confounders between the groups and because of the inadequate sample size. This limitation reduces the ability to generalize or to make causal inferences. In summary, this study describes the effects of care bundle implementation as a bundle of positioning and not each position individually. Finally, it would be better to confirm the hemodynamic findings with Doppler USG and NIRS. These findings should be regarded as preliminary or pilot, and while they showed evidence in favor of the NCB, our results still cannot be interpreted definitively, so further studies demonstrating causality should be planned. Strengths of this study was that the cUS of all the patients were evaluated by the same two neonatologists. However, evaluations and the classification of the images were verified by an external expert. By performing the cUS within six hours of admission, cases with intrauterine hemorrhage were excluded from the study, and, thus, the effect of NCB was demonstrated more clearly.

CONCLUSIONS

This study suggests a potential benefit of NCB in reducing GM-IVH. It also suggests that increasing awareness, standardization, and modifying neonatal care during the period of highest IVH risk in preterm infants may affect GM-IVH rates. These findings should be regarded as preliminary and hypothesis-generating, highlighting the need for prospective, multicenter studies. ■

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