—**Original**—

Statistical Evaluation of the First Year of a Neonatal Intensive Care Unit Established in a Medical School Hospital

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Background: There has been significant progress in reducing perinatal mortality in Japan. However, due to changes in social conditions, the total fertility rate and the number of births are decreasing, whereas the number of low birth weight infants is increasing along with the number of newborn babies that require intensive care. Further, although the number of high-level perinatal medical centers has increased, so has that of infants who need long-term hospitalization. Conversely, the number of regular obstetric facilities has decreased, thus resulting in insufficient beds for neonatal care. To fill this gap, we established a neonatal intensive care unit (NICU) at our hospital. This study aimed to evaluate our new type by comparing the data from ours with that from other facilities.
Methods: The other facilities assessed were two high-level NICU facilities and two regular obstetric facilities. Data, including sex, gestational age, birth weight, Apgar scores at 1 and 5 min, delivery method, and presence of breathing disorders, were extracted from medical records.
Results: The birth weight and gestational age distributions were significantly different in the institutions, except in one facility without a NICU. The new NICU saw more infants with low birth weight and respiratory disorders than the regular obstetric facilities.
Conclusion: The comparison of birth weight and gestational age distributions, cases of respiratory disorders, and delivery methods indicate that our new NICU is positioned as an intermediate facility between a high-level NICU and a regular obstetrics facility. (J Nippon Med Sch 2021; 88: 283–290)

Key words: NICU, neonatal intensive care unit level, neonate, respiratory disorder

Introduction

In Japan, high-risk neonatal medical services were initiated in the 1950s, and the progress in neonatal medicine in recent decades has been remarkable. Due to the development of perinatal medical systems[1,2], respiratory aids for newborns[3,4], and artificial lung surfactants[5], Japan's neonatal mortality rate has declined significantly, and is now one of the best in the world. Japan has an aging society with a declining birthrate, and the number of births has fallen below 1 million per year. Conversely, the number of high-risk pregnancies and low birth weight infants is increasing[6], in turn causing an increment in the number of neonates who need long-term hospitalization causing a critical lack of hospital beds[7]. In addition, the number of obstetricians and gynecologists is considered to have decreased due to social issues such as litigation problems and overwork, along with the number of hospitals and clinics equipped for effective management

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during delivery[8]. According to statistical data from the Japanese Ministry of Health, Labor and Welfare, the total number of hospitals and clinics equipped for childbirth decreased from 5,451 to 4,640 (by 15%) in 10 years from 2008 to 2017[9]. Further, although neonatal intensive care units (NICUs) that manage premature and low birth weight infants are being established, maternity hospitals that manage normal newborns are also scarce. Currently, the total fertility rate in Japan continues to decline and is below 1.5 children per woman, and the proportion of low birth weight infants, which was approximately 5% in 1975, doubled by 2016 to approximately 10%.

To address this nationwide healthcare requirement, we established a NICU for high-risk deliveries at our hospital to bridge the gap between high-level NICUs and normal newborn facilities. The NICU + Growth Care Unit (GCU) of our hospital was started with 9 beds targeting newborns with a birth weight of 2,000 g or more after 35 weeks. However, after the unit was established, we found that some of the newborns were below this standard, and the criterion was changed to an estimated body weight of 2,000 g after 34 weeks of gestation.

Materials and Methods

Facilities Studied

The facilities investigated in this study were the recently established NICU (NICU 3 beds, GCU 6 beds) in the main university hospital (New NICU), the University Hospital's Maternal and Child Perinatal Center (NICU 6 beds, GCU 12 beds; NICU-A), and the Mother and Child Perinatal Center (NICU 12 beds, GCU 20 beds; NICU-B) and the university hospital with no NICU (No-NICU-A) and community hospital with no NICU (No-NICU-B).

Our hospital is a prominent university hospital located in the center of Tokyo, wherein a considerable number of patients with congenital heart diseases have been treated by pediatricians and cardiac surgeons in the absence of a NICU. The recently established NICU is currently managed by pediatricians without full-time neonatologists. NICU-A is a university hospital branch that has a NICU with full-time neonatologists and pediatric surgeons who manage surgical cases. NICU-B is a facility specializing in high-level perinatal medical care that has a NICU with full-time neonatologists; however, there are no pediatric surgeons, and thus, surgical cases presenting to this center are transferred. No-NICU-A is a university hospital branch in the suburb and a general hospital equipped with an advanced emergency medical service center; however, there is no neonate specialist, although there is a facility with NICU nearby, and thus, high-risk pregnancies are not managed at No-NICU-A. No-NICU-B is a general hospital in Tokyo; however, there are no neonatologists, and the pediatricians only examine outpatients.

Subjects

In-hospital births at five facilities were included in the study, and transfers to other hospitals and stillbirths were excluded. For comparison, we referred to the Mother and Child Statistics Report of 2015 by Tokyo Metropolitan that was published in 2019[10]. This report includes the information from all births in the Tokyo metropolitan area.

Data acquisition and Statistical Analyses

Data, including sex, gestational age, birth weight, Apgar score at 1 and 5 min, delivery method, and presence of breathing disorder, were extracted from medical records and investigated. Newborn information from 5 facilities and Tokyo metropolitan was compared by Fisher's exact test.

The distribution of the birth weights and gestational age in our hospital and the other four medical institutions was analyzed by the Mann-Whitney U test. When the P value was 0.05 or less, it was determined that there was a significant difference. Fisher's exact test was used to assess the relative risk (RR) and odds ratio (OR) for respiratory disorders. Statistical analysis was performed using GraphPad Prism 8®, and XLSTAT®.

Results

Information regarding newborn babies at the 5 facilities from January 2018 to December 2018 and the data of Tokyo metropolitan are summarized in **Table 1**, and each facility's admission criteria are compared in **Table 2**. The total number of newborns at our hospital was 466, with 238 girls (51.1%), 228 boys (48.9%); there were 12 twins (2.6%). The number of women with normal vaginal delivery was 244 (52.4%), scheduled cesarean section (SCS) 108 (23.2%), emergency cesarean section (ECS) 73 (15.7%), vacuum delivery (VD) 40 (8.6%), and forceps delivery (FD) 1 (0.2%). The birth weight of the infants managed in our hospital ranged from 1,630 g to 4,506 g (average 2,947.2 g, standard deviation 458, median 2,964 g), and 66 infants had low birth weight (14.2%). Smaller children were transferred to a high-level NICU. The gestational ages ranged from 34.0-42.1 weeks (mean 39.1 weeks, median 39.1 weeks). The Apgar score at 1 minute was generally normal (score $\geq$7; 437 [93.8%]), but indicated mild neonatal asphyxia (score, 4-6) in 10 (2.1%) and severe

Table 1 Comparison of the total number of deliveries, sex, delivery mode, birth weight, gestational age, and Apgar scores at the five target facilities

		Information of delivery (Jan 1st ~ Dec 31st, 2018)						
		New NICU	NICU-A	NICU-B	No-NICU-A	No-NICU-B	Total bitrth of Tokyo (2016)	All Tokyo Perinatal Maternal and Child Medical Center (27 facilities, 2016)
Total number of births		466	757	537	117	259	111,962	29,451
Sex	Female	238 (51.1%)	363 ns (48.0%)	240 * (44.7%)	52 ns (44.4%)	119 ns (45.9%)	no data	no data
	Male	228 (48.9%)	394 (52.0%)	297 (55.3%)	67 (57.3%)	140 (54.1%)		
Twin		12 (2.6%)	46 ** (6.1%)	70 **** (13.0%)	0 ns (0.0%)	0 ** (0.0%)		
Delivery mode	NVD	244 (52.4%)	365 **** (48.2%)	167 **** (30.9%)	62 *** (53.0%)	186 **** (71.8%)		20,010 **** (68.0%)
	SCS	108 (23.2%)	129 ** (17.0%)	81 ** (15.1%)	23 ns (19.7%)	31 ns (12.0%)		4,727 **** (16.1%)
	ECS	73 (15.7%)	199 **** (26.3%)	252 **** (46.9%)	18 ns (15.4%)	31 ns (12.0%)		4,714 ns (16.0%)
	VD	40 (8.6%)	62 ns (8.2%)	35 ns (6.5%)	13 ns (11.1%)	6 *** (2.3%)		no data
	FD	1 (0.2%)	3 ns (0.4%)	2 ns (0.4%)	1 ns (0.9%)	5 ns (1.9%)		
	others	3 (0.6%)	1 ns (0.1%)	0 NA (0.0%)	0 NA (0.0%)	0 NA (0.0%)		
	LBW	66 (14.2%)	99 ns (13.1%)	281 **** (52.3%)	12 ns (10.3%)	14 *** (5.4%)	9,528 **** (8.5%)	no data
	VLBW	0 (0.0%)	49 **** (6.5%)	31 **** (5.8%)	0 NA (0.0%)	0 NA (0.0%)	447 ns (0.4%)	
	ELBW	0 (0.0%)	31 **** (4%)	15 **** (2.8%)	0 NA (0%)	0 NA (0%)	318 ns (0.3%)	
Birth body weight (g)	range	1,630-4,506	520-4,576	470-4,030	2,300-4,300	1,730-4,134	no data	no data
	mean (SD)	2,947.2 (458.0)	2,813.3 (595.9)	2,517.1 (682.8)	2,995.7 (341.9)	3,104.7 (399.4)		
	median	2,964	2,897	2,548	2,980	3,074		
Gestational age (weeks)	range	34.0-42.1	25.1-41.9	24.0-42.0	35.4-41.4	36.3-41.9		
	mean (SD)	39.1 (1.47)	38.2 (2.64)	36.9 (3.13)	39.0 (1.14)	39.6 (1.22)		
	median	39.1	38.6	37.3	39.0	39.7		
Apgar score								
1min	Generally normal (≧7)	437 (93.8%)	732 ** (96.7%)	476 ** (88.6%)	115 * (98.3%)	255 *** (98.5%)		
	Mild neonatal asphyxia (4-6)	10 (2.1%)	19 ns (2.5%)	48 **** (8.9%)	1 **** (0.9%)	3 **** (1.2%)		
	Severe neonatal asphyxia (<4)	23 (4.9%)	8 **** (1.1%)	17 ns (3.2%)	1 ns (0.9%)	1 *** (0.4%)		
5min	Generally normal (≧7)	450 (96.6%)	754 * (99.3%)	524 ns (97.6%)	117 ns (100.0%)	259 * (100.0%)		
	Mild neonatal asphyxia (4-6)	5 (1.1%)	3 ns (0.4%)	14 ns (2.6%)	0 NA (0.0%)	0 NA (0.0%)		
	Severe neonatal asphyxia (<4)	4 (0.9%)	0 NA (0.0%)	3 ns (0.6%)	0 NA (0.0%)	0 NA (0.0%)		

NVD: normal vaginal delivery; SCS: scheduled cesarean section; ECS: emergency cesarean section; VD: vacuum delivery; FD: forceps delivery; NA: not applicable
ns, P>0.05; *, P ≤0.05; **, P ≤0.01; ***, P ≤0.001; ****, P ≤0.0001

Table 2　Comparison of admission criteria of 5 facilities

	The beds number of NICU+ GCU	Gesta- tional age	Birth weight	mul- tiple birth	surgical neonates			Respiratory disorder	Perinatal infection risk factor	Prominent jaundice	Feeding difficulties	Doctor's judgment
					Plastic	Cardiac	GI					
NewNICU	9	>33 w	>1,500 g	○	△	○	×	○	○	○	○	○
NICU-A	18	>22 w <36 w	no restricion	○	△	△	○	○	○	○	○	○
NICU-B	32	>22 w <36 w	no restricion	○	△	△	×	○	○	○	○	○
no-NICU-A	0	>35 w	>2,300 g	△	△	△	×	×	○	○	○	○
no-NICU-B	0	>34 w	>2,100 g	×	△	×	×	×	○	○	○	○

GI: gastrointestinal

Symbols shows; ECS: circle: acceptable, triangle: acceptable depending on case, cross: not acceptable

neonatal asphyxia (score, <4) in 23 (4.9%). Similarly, the Apgar score at 5 minutes was generally normal (≥7; 450 [96.6%]), but indicated mild neonatal asphyxia in 5 (1.1%) and severe neonatal asphyxia in 4 (0.9%). Information regarding the other four facilities are shown in **Table 1**.

In birth body weight comparison, NICU-B managed significantly more LBW than other facilities. The rate of LBW managed in our NICU was significantly higher frequency than the LBW rate of Total birth of Tokyo metropolitan (in 2015). In delivery mode comparison, the frequency of NVD was less than the frequency of All Tokyo Perinatal Maternal and Child Medical Center (27 facilities, in 2016), and the frequency of cesarean section of our NICU was more.

The distribution of the birth weight and gestational age was not significantly different between No-NICU-A and our hospital's NICU. Conversely, the distribution was different in all the other facilities when compared with that in our hospital. The distribution of gestational week was not significantly different between No-NICU-A and our hospital's NICU. However, the distribution was significantly different from NICU-A, NICU-B and No-NICU-B (**Fig. 1**).

It seems that there is no significant difference between no-NICU-A and our NICU, However, in fact, there is a big difference between these facilities. In our hospital, there are 8 cases of congenital heart disease; atrioventricular septal defect, tetralogy of Fallot, Transposition of the great arteries, Ventricular septal defect, etc. Five cases have been operated by our pediatric cardiovascular surgeons, and the other three cases have been followed up in pediatric outpatient. On the other hand, in no-NICU-A, if a fetus requiring cardiac surgery is found out with echo diagnosis, mother will be referred to another hospital at the time. And If they are discovered after birth, they will be transported to the high level NICU.

Next, the RR and OR for respiratory disorders, including respiratory distress syndrome, transient tachypnea of the newborn, and meconium aspiration syndrome, were assessed according to groups based on the delivery method: emergency cesarean section (ECS), scheduled cesarean section (SCS), and normal vaginal delivery (NVD) (**Table 3a, b, c, d**).

No significant difference between ECS and SCS was noted in our hospital's NICU. In the comparison between ECS and NVD, the RR was 4.2 and OR was 4.7, and that between SCS and NVD showed an RR of 3.7 and OR of 4.1 (**Table 3c**). There was a significant difference between ECS and SCS + NVD with an RR of 2.3 and OR of 2.5 (**Table 3d**).

Discussion

When comparing the five facilities and the data of Tokyo metropolitan with regards to the method of delivery, the new NICU in our hospital and no-NICU-A had a significantly higher frequency of SCS than in other institutions and All Tokyo Perinatal Maternal and Child Medical Center, which are high-level perinatal facilities (**Table 1**). Conversely, the frequency of ECS was significantly higher in NICU-A and NICU-B than in other facilities. In addition, two facilities, NICU-A and NICU-B, delivered several twins, especially NICU-B, in which the percentage exceeded 10%. These two NICU facilities saw many ECS cases with high-risk deliveries such as those of preterm and low birth weight infants and twins, and pregnancies with complications. In addition, since No-NICU-A saw a small number of deliveries and has no neona-

Table 3a, b The number of respiratory disorder cases according to the delivery method at the five target facilities

a. All patients.

	newNICU		NICU-A		NICU-B		no NICU-A		no NICU-B	
	RD	NP	RD	NP	RD	NP	RD	NP	RD	NP
ECS	10	63	60	139	194	58	4	14	6	25
SCS	13	94	12	117	53	28	0	23	3	28
NVD	8	236	29	336	79	88	1	61	9	177
VD	3	37	4	58	20	15	1	12	1	5
FD	0	1	0	3	1	1	0	1	1	4
Total	34	431	105	653	347	190	6	111	20	239

b. Patients delivered after 34 weeks of gestational age.

	newNICU		NICU-A		NICU-B		no NICU-A		no NICU-B	
	RD	NP	RD	NP	RD	NP	RD	NP	RD	NP
ECS	10	63	29	127	142	52	4	14	6	25
SCS	13	94	12	117	53	28	0	23	3	28
NVD	8	236	22	336	68	81	1	61	9	177
VD	3	37	4	58	20	15	1	12	1	5
FD	0	1	0	3	1	1	0	1	1	4
Total	34	431	67	641	284	177	6	111	20	239

ECS: emergency Caesarean section SCS: scheduled Caesarean section NVD: normal vaginal delivery

VD: vacuum delivery FD: forceps delivery

RD: respiratory disorder NP: nothing particular

Table 3c, d Relative risks and odds ratios between delivery modes and respiratory disorders

c. All patients.

Relative Risk (95%CI)	New NICU	NICU-A	NICU-B	no-NICU-A	no-NICU-B
ECS vs SCS	ns	6.5 **** (3.639 to 11.66)	1.2 * (1.008 to 1.425)	NA	ns
ECS vs NVD	4.2 ** (1.748 to 9.878)	3.8 **** (2.533 to 5.699)	1.6 **** (1.379 to 1.953)	13.8 ** (2.172 to 88.01)	4.0 * (1.545 to 9.878)
SCS vs NVD	3.7 ** (1.618 to 8.467)	ns	1.4 ** (1.095 to 1.726)	ns	ns
ECS vs SCS+NVD	2.3 * (1.128 to 4.525)	4.6 **** (3.186 to 6.572)	1.4 **** (1.268 to 1.662)	18.9 ** (2.953 to 120.7)	3.5 * (1.417 to 8.164)
Odds ratio (95%CI)					
ECS vs SCS	ns	8.8 **** (4.574 to 17.01)	1.8 * (1.026 to 2.987)	NA	ns
ECS vs NVD	4.7 ** (1.699 to 12.19)	5 **** (3.046 to 8.205)	3.7 **** (2.420 to 5.723)	17.4 ** (2.417 to 215.4)	4.7 * (1.483 to 14.35)
SCS vs NVD	4.1 ** (1.584 to 9.789)	ns	2.1 ** (1.237 to 3.597)	ns	ns
ECS vs SCS+NVD	2.5 * (1.154 to 5.382)	6.1 **** (3.941 to 9.522)	2.9 **** (1.982 to 4.290)	24 ** (3.351 to 295.5)	4.1 * (1.383 to 12.28)

d. Patients extracted after 34 weeks of gestational age.

Relative Risk (95%CI)	New NICU	NICU-A	NICU-B	no-NICU-A	no-NICU-B
ECS vs SCS	ns	2 * (1.082 to 3.742)	ns	NA	ns
ECS vs NVD	4.2 ** (1.748 to 9.878)	3 **** (1.803 to 5.059)	1.6 **** (1.331 to 1.965)	13.8 ** (2.172 to 88.01)	4.0 * (1.545 to 9.878)
SCS vs NVD	3.7 ** (1.618 to 8.467)	ns	1.4 ** (1.126 to 1.813)	ns	ns
ECS vs SCS+NVD	2.3 * (1.128 to 4.525)	2.7 **** (1.678 to 4.191)	1.4 **** (1.200 to 1.620)	18.9 ** (2.953 to 120.7)	3.5 * (1.417 to 8.164)
Odds ratio (95%CI)					
ECS vs SCS	ns	2.2 * (1.068 to 4.453)	ns	NA	ns
ECS vs NVD	4.7 ** (1.699 to 12.19)	3.5 **** (1.944 to 6.177)	3.3 **** (2.087 to 5.036)	17.4 ** (2.417 to 215.4)	4.7 * (1.483 to 14.35)
SCS vs NVD	4.1 ** (1.584 to 9.789)	ns	2.3 ** (1.296 to 3.925)	ns	ns
ECS vs SCS+NVD	2.5 * (1.154 to 5.382)	3 **** (1.779 to 5.099)	2.5 **** (1.642 to 3.693)	24 ** (3.351 to 295.5)	4.1 * (1.383 to 12.28)

"ECS vs. SCS" comparison for No-NICU-A could not be conducted because there were no cases of respiratory disorders associated with SCS.

ECS: emergency Caesarean section; SCS: scheduled Caesarean section; NVD: normal vaginal delivery; VD: vacuum delivery; FD: forceps delivery;

RD: respiratory disorder; NP: nothing particular.

ns, P>0.05; *, P ≤0.05; **, P ≤0.01; ***, P ≤0.001; ****, P ≤0.0001

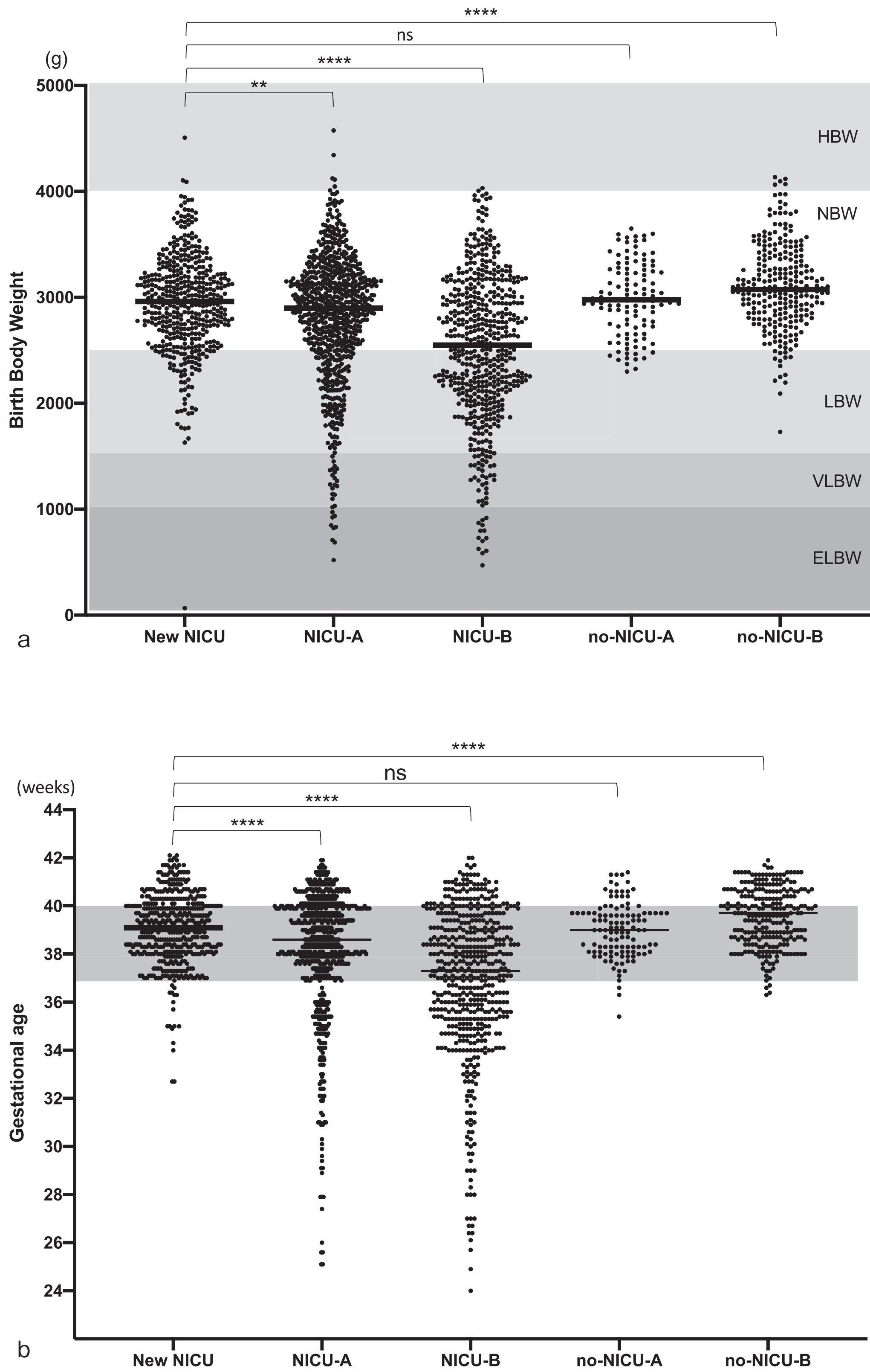

Fig. 1
a, Birth weight dispersion dots plot at the five facilities. b, Gestational age dispersion dots plot at the five facilities. Gray zone represents full term (37-40 weeks).
The horizontal lines represent the medians.
ns, P>0.05; **, P ≤0.01; ***, P ≤0.001; ****, P ≤0.0001
HBW: high birth weight; NBW: normal birth weight; LBW: low birth weight; VLBW: very low birth weight; ELBW: extremely low birth weight.

tologists, no cases of high-risk delivery due to the fetus were noted, and the rate of SCS due to maternal complications was high. No-NICU-B tended to see a low proportion of cesarean sections presumably because there is no neonatologist and no beds for pediatric inpatients at this facility. Further, No-NICU-B has no pediatrician on night duty, and thus, high-risk deliveries are not managed here, there are few cases of cesarean section, and normal vaginal delivery is mainly performed.

The distributions of birth weight and gestational age at the new NICU, NICU-A, NICU-B, and No-NICU-B were significantly different; however, no difference from that in No-NICU-A was noted. In the comparison between the new NICU and No-NICU-A, there was no significant difference in statistical variance, but the former saw more low birth weight and preterm infants and those with respiratory disorder (31 cases vs. 5 cases).

In general, NVD is often recommended for mature babies, while SCS applies to non-urgent maternal and neonatal complications. Conversely, ECS is indicated when the child and mother are both at risk[11]. Therefore, the proportion of premature birth and low birth weight infants increases along with the number of ECS cases. In the comparison according to the delivery method and risk of respiratory disorder, NICU-A and NICU-B tended to show a high RR and OR for cesarean section owing to the high number of preterm and low birth weight infants. The difference between New NICU and other facilities is not significant difference when analysis is performed on infants with birth weight of 2,000 g or more after 34 weeks of gestation in NICU-A and NICU-B according to the new NICU standard. In previous reports[12], showed that selective cesarean delivery was a risk factor for respiratory illnesses such as transient tachypnea in newborns. At our New NICU, there was no significant difference between ECS and SCS, however there was a significant difference between cesarean section and NVD, as previously reported.

Conclusion

A new NICU was recently established at our hospital for high-risk deliveries to bridge the gap between high-level NICUs and regular obstetric facilities without a NICU. Infants over 34 weeks of gestational age were enrolled for this analysis. Based on our comparative study, our new NICU was positioned as an intermediate facility between a high-level NICU and a regular obstetrics facility without NICU. The number of deliveries is on the decline, but high-risk deliveries are increasing in recent Japan[13].

In order to provide more safety care for pregnant women and newborns, it is desirable to equip facilities that cover “gaps” that cannot be managed by high-level NICUs or regular obstetric facilities. Our facility is conformed to bridge the gap between high-level NICUs and regular obstetric facilities without NICU. And it is hoped that the work-life balance for the obstetrician, neonatologist and pediatrician will be improved.

Conflict of Interest: The authors declare that they have no conflict of interest.

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