

Predictive Value of Developmental Quotient at Three Months in Determination of Neurodevelopmental Outcomes at One Year in High-Risk Neonates

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ABSTRACT

Background: High-risk neonates need intervention to improve their development.

Objective: To compare the neurodevelopmental outcomes at one year of age in high-risk babies (cases) and normal babies (control group).

Study design: Case comparison study.

Material and methods: Two groups of participants were formed by simple random sampling: one composed of 245 high-risk babies (cases) and the other one of 245 normal babies (controls). Babies were stratified into high and low risk according to the medical diagnosis given in the neonatal intensive care unit and at three months. Standard care was offered to both groups, and subjects in the high-risk group has additionally received stimulation programs from their mother, who were trained. A monthly follow-up of the stimulation program was done. Therapist involvement was needed when the delay was observed despite stimulation given by the mother.

Outcomes: Stimulation programs given since birth improve mental and motor development quotient (DQ).

Results: Results were interpreted taking the DQ of 70 as a cut-off value for assessing developmental delay. McNemar's test was used to compare changes in proportions of pre- and post-stimulation abnormal outcomes. After one year, a significant reduction in mental developmental delay was observed in both

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high- and low-risk groups (35.1% and 45.9%, respectively), with this reduction being similar in the two groups as 95% confidence intervals for change in the proportion of developmental delay were overlapping. Likewise, motor development delay has also significantly decreased in both groups by 32.9% and 41.9%, respectively.

Conclusion: Indian Standardized Stimulation Programs considering the mother as a therapist helps improve neurodevelopmental outcomes based on DQ assessment using the Developmental Assessment Scale for Indian Infants (DASII), an Indian modification of Bayley scale of infant development (BSID).

Keywords: neurodevelopmental outcome, Indian Standardized Stimulation Program, mother as a therapist, predictive value of DQ, high-risk neonate stratification.

INTRODUCTION

Child development and maturation Child development is a dynamic process of optimally utilizing the genetic potential within the context of the environment made available to enable him/her to achieve the full potential. However, the first year of life and pre-school years forms the most critical period in a child's development, which is a continuous process. The tricky part is identifying babies at risk for poor development (1).

How a person expresses the urge to become healthy depends on the individual's innate abilities and training. Every child is said to be the interplay between genetic and environmental factors, with genes setting the limits of achievement and the environment determining whether he/she achieves it or not (2).

Maturation unfolds a person's inherent traits, while learning is the development that comes from exercise and effort on the individual's part (3).

Unless environmental conditions prevent it, the development will follow a similar pattern for all, which makes it possible to predict what people will do at a given age. Every person is biologically and genetically different from every other human being, even in identical twins (4).

High-risk criterion and optimality

The risk factor is an attribute or exposure that is significantly associated with disease development (5). The concept of "optimality may replace the concept of «at-risk» newborns." Newborns with a low "optimality score" are considered highly likely to develop neurodevelopment disabilities later in life. However, it must be remem-

bered that many of the babies not considered "at-risk" may also manifest developmental problems as they grow, and they would not be seen during "at-risk" focused follow-up screening (6).

There is a need to identify high-risk newborns, and hence this study has been conducted. High-risk identification helps neonates to get more attention in the form of screening and early intervention.

Types of risk factors

Risk factors are stratified into three main categories: a) biological risk factors, including prematurity, low birth weight, asphyxia, shock, need for ventilation, sepsis, jaundice, patent ductus arteriosus, necrotizing entero-colitis, malformations (7); b) interventions (risk factors due to interventions), e.g., post-natal steroids/hypocarbica; and c) socio-economic risk factors, including mother's and father's education, family type, family income, and quality times spent by parents.

Various risk factors have been identified for adverse developmental outcomes in neonatal intensive care unit (NICU) graduates, among which gestational age and birth weight are probably the most significant ones. Although a remarkable improvement in very low birth weight and extreme low birth weight babies has been seen, it was not associated with a similar improvement in neurodevelopmental outcomes. Hence, most centers treat the neurodevelopmental outcome as a measure of success and undertake follow-up preterm (8).

In various studies, isolated factors were explored, but in the present researcher has included a maximum number of factors together and studied their outcome in the form of mental and motor DQ, vision, and hearing abnormality. □

MATERIAL &METHODS

Study design: Case comparison study
Study settings: The present study was carried out at Sant Dyaneshwar Medical Education Research Center, which is a 18 bedded NICU accredited by the National Neonatology Forum, with three ventilators, a yearly turnover of 400 admissions to NICU, and 1 000-1 500 babies in the well-baby clinic.

Study period: three years

Sampling: A special high-risk clinic was run by a team of developmental pediatricians, neonatologists, psychologists, physiotherapists and occupational therapists, ophthalmologists, audiologists, and social workers. The neonatologist and the developmental pediatrician were responsible for the complete coordination of the follow-up. Both high-risk and healthy babies attended the clinic during the study period. Along the study period, 960 babies were admitted to NICU, of which 245 were enrolled as cases by simple random sampling. The same technique was used to select the 245 controls from a total of 3 050 healthy outpatient children below one year of age (Figure 1).

Effective sample: The present research is a case comparison study that tests several risk factors as predictors of a neurological outcome. Sample size calculations were based on differences in motor and mental development scores between three months and one year. The sample size was calculated to detect a difference in motor and metal scores of 0.3 SD (9). Using the PS program for performing power and sample size calculations enabled us to obtain a sample size of 234 in each group at 5% significance and 90% power, but considering withdrawals, refusals and losses to follow up, we decided to enroll 245 subjects in each group.

High-risk and normal babies were randomly selected using the computer-generated sequence. Neurodevelopmental outcome was studied on mental and motor developmental quotient, hearing, and vision (10).

In the present study, the Developmental Assessment Scale for Indian Infants (DASII), an Indian modification of Bayley Scale of Infant Development (BSID), was used to assess the mental and motor developmental quotient (DQ). Given that BSID (DASII) has long been considered the standard criteria for the developmental assessment of infants and subsequent diagnosis of cog-

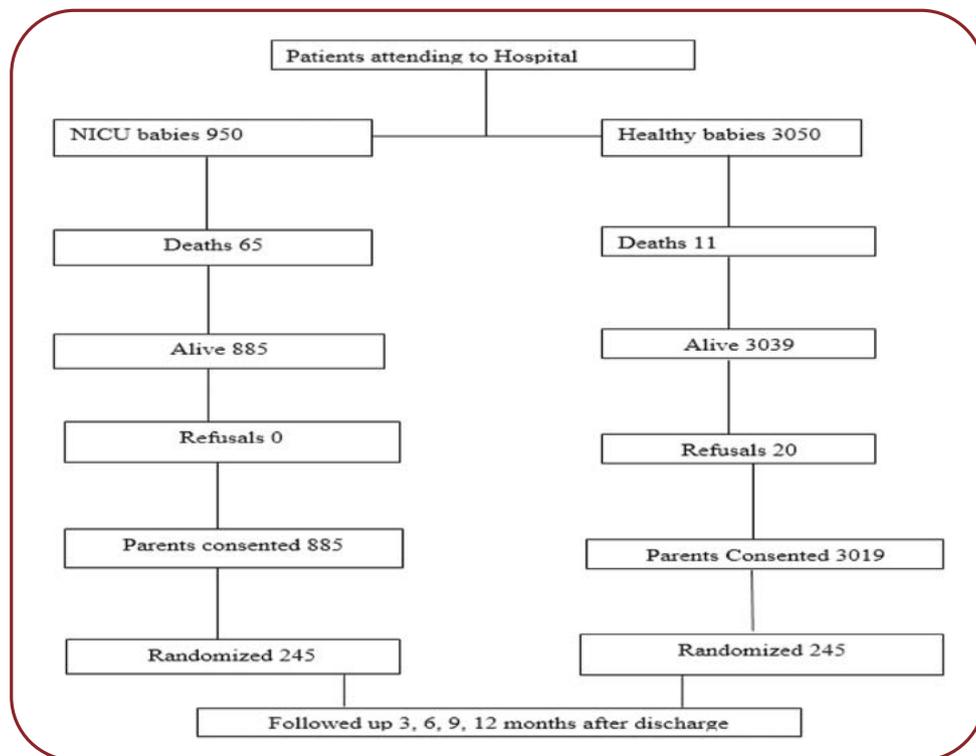


FIGURE 1. Flow chart showing selection of subjects

nitive-motor delays, it should be used as a proper tool during the first year of life.

According to the study of Malgorzata Augustyniak *et al* (11), the developmental delays at the end of the first year, which have been identified by using BSID (DASII), may indicate a moderate probability of continuing delays.

Ethics and consent: The present study was approved by the hospital Ethics Committee. The purpose of the study was explained to parents of all participants, and informed verbal consent was taken from each of them before enrolling their children in the study.

Parents of participants were educated before discharge from NICU about potential risk factors for adverse neurodevelopmental outcomes and the need for structured follow up. They were informed that all data regarding their babies was recorded for research purposes, and were asked to follow monthly for stimulation program and at three month-interval for developmental assessment.

Data collection: Every case and control participant was assessed at 3, 6, 9 and 12 months. Weight, height, and head circumference measurements were done. Socio-demographic, family and developmental history was taken. Cases were stratified into high- and low risk according to medical diagnosis earned in NICU and at three months. They were assessed by neurological evaluation, active and passive tone as well as reflexes. Administration of BSID (DASII) was done for every child. Results were interpreted taking a developmental quotient of 70 as a cut-off value for assessing developmental delay; that cut off should be used to find the developmental delay classified based on mental development index (MDI) scores <70 BSID (DASII) cut-offs used for outcome measure (12, 13).

All neurological assessments and psychomotor tests were done during the clinic visit. In addition, immunization was given during the same visit. All possible efforts were made to minimize visits to hospital. A letter was sent one week before the appointment for testing, and mobile calls were made the day before as reminders for the parents. Standard care was given to both groups, and additionally the high-risk group received stimulation programs and intervention.

Mothers of high-risk babies were taught how to give two stimulation programs: the Marathi version of CDC Trivandrum and Hindi version of

the Indian National Portage Association. Printed copies of the programs were given to them, and they were asked to mark passed and failed items by a blue and red circle, respectively. In addition, they were asked to draw a green circle in front of the red circle when that item was achieved as a result of the intervention. A monthly follow up of the stimulation program was done. Involvement of the therapist was needed when a delay was observed despite stimulation given by the mother.

Inclusion and exclusion criteria

Selection of cases (Table 1): Babies with NICU graduates were chosen as cases.

The risk criterion by NNF was used for this study to select cases as follows (14): birth weight < 2.5 kg, gestational age < 37 weeks, asphyxia neonatorum (Apgar score <5 at five minutes), hyperbilirubinemia, septicemia, meningitis, intraventricular hemorrhage, respiratory distress, convulsions (single or multiple), apnea (single or multiple), meconium aspiration, ventricular septal defect, atrial septal defect, patent ductus arteriosus.

Selection of control: full-term gestational age, birth weight of more than 2 500 grams, normal antenatal, natal, and postnatal course

Exclusion criteria: lost to follow up and deaths

Techniques and tools for data collection

Bayleys Scale of Infant Development Indian norms (DASII); hearing screening by evoked otoacoustic emissions (OAE) and confirmation by brainstem evoked response audiometry (BERA).

OAE (15): Evoked otoacoustic emissions are acoustic signals generated from within the cochlea that travel in the reverse direction through the middle ear space and tympanic membrane out to the ear canal. These signals are generated in response to clicks or tone bursts and may be detected with a susceptible microphone/probe system placed in the external ear canal. The OAE test allows for individual ear assessment. It is performed quickly at any age and is not dependent on whether the child is asleep or awake. Motion artifact does not interfere with test results. The OAE is an effective screening tool for inner and middle ear abnormalities. At the hearing threshold (30 dB) there is no OAE response. The OAE test does not further quantify hearing loss or hearing threshold level. Also, it

does not access the integrity of the neural transmission of sound from the eighth nerve to the brainstem – therefore, it will miss auditory neuropathy and other neuronal abnormalities. Infants with such abnormalities will have normal OAE test results but abnormal BERA test results.

BERA (15): Brainstem evoked response audiometry is an objective means of evaluating hearing. This instrument measure evokes a response in response to sound clicks at frequencies greater than 1 000 Hz. The automated screener provides a pass-fail report, and no test interpretation by an audiologist is required. Automated BERA can test each ear individually and can be performed on children of any age. Motion artifact interferes with the test result. For this reason, the test is performed best in infants and young children while they are sleeping or, if necessary, sedated. The BERA and OAE are useful for the auditory pathway structural integrity but they are not accurate hearing tests. Even if BERA or OAE test results are normal, hearing cannot be definitively considered normal until a child is mature enough for a reliable behavioral audiogram to be obtained. Behavioral pure tone audiometry remains the standard for a hearing evaluation. Children as young as 9 to 12 months can be screened by means of conditioned oriented responses (CORs) or visual reinforced audiometry (VRA).

Vision and ROP testing

Intervention was given by physiotherapist, speech therapist, and occupational therapist as per requirements of babies. Marathi version of the CDC model of early intervention (16) and Hindi version of the Standardized Stimulation Program Portage Education by the Education Department were used. There is also an international program given in more than 90 countries (University of Chandigarh, Dr. Tehel Kohli) (17), which addresses the stimulation of six areas of child development [Shishu Prostan], including motor development [Sanchalan Vikas], language development [Bhashik Vikas], social development [Samajik Vikas], cognitive development [Dyanatmak Vikas], and self independent development [Swavlamban]. Parents could use this program as a checklist and plan stimulations at home, and they were clearly explained what to do through this program. Simulation programs were simple for all high-risk babies, with simple objects being available in every home.

Operational definitions

High risk – neonate admitted to NICU with more than three clinical diagnosis earned at NICU and three months of age

Low risk – neonate admitted to NICU with three or less than three clinical diagnoses earned at NICU and three months of age

Control – normal neonate with full-term and birth weight >2.5 kg; normal antenatal, natal, and postnatal course.

Stimulation program – Two programs were used: Trivandrum developmental stimulation program from CDC Trivandrum (Marathi version) and Portage Association from Chandigarh (Hindi version developed by Indian National Portage Association).

Intervention program – given to babies who did not show good response using only stimulation programs; they include stimulation program plus therapies offered by physiotherapists, speech therapists, and occupational therapists.

Statistical analysis

We selected babies by simple random sampling. Those with DQ (using DASII) below 70 were classified as abnormal. Data are presented as mean (SD) for normally distributed variables and median (25th–75th percentile) for those not normally distributed. The normality of continuous variables was ensured during statistical analysis. Baseline characteristics were compared between the groups using the chi-square test (χ^2) for categorical variables and the independent sample t-test when data was continuous.

Bonferroni correction was done since the numbers of repeated measures were more than two. Repeated measurement analysis was adjusted for gender. ANOVA analyzed the significance of the difference between the means of the two groups with adjustments for confounding variables (age, gender, socio-economic status) as appropriate. DQs at three months and one year compared by paired t-test and 95% confidence intervals (CIs). Change in proportion of abnormal DQ at one year was tested by McNemar's test and confidence interval one year there was a significant reduction in those with mental and motor developmental delay.

Analysis was carried out with the statistical package for social sciences for Windows (SPSS, Chicago Ill), version 21, and STATA version 11.1 software (STATA Corporation, College Station, TX).

All p values were two-tailed, and the significance threshold of P=0.05 was used in all analyses. □

RESULTS

Results of birth outcome: preterm and low birth weight and neurological outcome

In Table 1 there was a significant reduction in the prevalence of abnormal motor and mental DQ between 3 and 12 months among preterm or LBW children.

Bayley's Scale of Infant Development to assess neurodevelopmental outcome

Mental developmental quotient – Table 2 shows quotient classification. There was a significant re-

duction of 35.1% in high- and low-risk groups, 45.9% in abnormality after 12 months (Table 3). This reduction was similar as 95% confidence intervals were overlapping.

Motor developmental quotient – Table 4 shows quotient classification. There was a significant reduction of 32.9% in high- and low-risk groups, 41.9 % in abnormality after 12 months. This reduction was similar in both groups as 95% confidence intervals were overlapping (Table 5).

Results of neurodevelopmental outcome: hearing and vision

The prevalence of deafness and blindness was 1.6% and 0.8%, respectively. □

TABLE 1. Prevalence and change in prevalence of BSID (DASII) motor and mental DQ abnormality in preterm and low birth weight (LBW) neonates over the intervention period

Abnormal mental and motor DQ	Mental DQ				Motor DQ			
	Preterm (n=78)		LBW (n=125)		Preterm (n=78)		LBW (n=125)	
	N	%	n	%	N	%	n	%
3 months	44	56.4	68	54.4	56	71.8	84	67.2
12 months	15	19.2	18	14.4	21	26.9	32	25.6
Change	-29	-37.2	-50	-40.0	-35	-44.9	-52	-41.6
p for change	0.000		0.000		0.000	0.000	0.000	0.000
95% CI for % change	-49.1, -25.1		-49.3, -30.6		-57.1, -32.6		-51.0, -32.1	

TABLE 2. Mental DQ classification

DQ range	NICU								Healthy babies			
	High-risk (n=97)				Low-risk (n=148)				Controls (n=245)			
	3 m		12 m		3 m		12 m		3 m		12 m	
	N	%	n	%	n	%	n	%	n	%	n	%
>140 Genius	-	-	-	-	-	-	-	-	-	-	-	-
120-140 Intelligent	-	-	-	-	-	-	-	-	-	-	-	-
110-120 Superior	-	-	-	-	-	-	1	0.7	-	-	75	30.6
90-110 Normal	4	4.1	27	27.8	8	5.4	33	22.3	207	84.5	170	69.4
70-90 Borderline	31	32	43	44.3	43	29.1	85	57.4	38	15.5	-	-
50-70 Mild	45	46.4	23	23.7	77	52.0	25	16.9	-	-	-	-
35-50 Moderate	12	12.4	3	3.1	11	7.4	3	2.0	-	-	-	-
20-35 Severe	5	5.2	1	1.0	9	6.1	1	0.7	-	-	-	-
<20 Profound	-	-	-	-	-	-	-	-	-	-	-	-

Age	High-risk (n=97)		Low-risk (n=148)		Controls (n=245)	
	N	%	N	%	n	%
3 months	62	63.9	97	65.5	0	0
12 months	27	27.8	29	19.6	0	0
Change	-35	-35.1	-68	-45.9	0	0
p for change	0.000		0.000		1.0	
95% CI for % change	-46.6, -25.4		-54.6, -37.2		-0.4, 0.4	

TABLE 3. Prevalence and change in prevalence of BSID (DASII) mental DQ below normal between 3–12 months

DQ range >90 as normal	NICU								Healthy babies			
	High-risk (n=97)				Low-risk (n=148)				Controls (n=245)			
	3 m		12 m		3 m		12 m		3 m		12 m	
	N	%	n	%	n	%	n	%	n	%	n	%
>140 Genius	-	-	-	-	-	-	-	-	-	-	-	-
120-140 Intelligent	-	-	-	-	-	-	-	-	-	-	3	1.2
110-120 Superior	-	-	2	2.1			2	1.4	-	-	83	33.9
90-110 Normal	4	4.1	27	27.8	4	2.7	42	28.4	207	84.5	159	64.9
70-90 Borderline	43	44.3	50	51.5	59	39.9	81	54.7	38	15.5	-	-
50-70 Mild	38	39.2	14	14.4	68	45.9	20	13.5	-	-	-	-
35-50 Moderate	4	4.1	4	4.1	10	6.8	2	1.4	-	-	-	-
20-35 Severe	8	8.2	-	-	6	4.1	1	0.7	-	-	-	-
<20 Profound	-	-	-	-	1	0.7		-	-	-	-	-

TABLE 4. Motor DQ classification

Age	High-risk (n=97)		Low-risk (n=148)		Controls (n=245)	
	N	%	N	%	n	%
3 months	50	51.5	85	57.4	0	0
12 months	18	18.6	23	15.5	0	0
Change	-32	-32.9	-62	-41.9	0	0
p for change	0.000		0.000		1.0	
95% CI for % change	-43.3, -22.6		-50.7, -33.0		-0.4, 0.4	

TABLE 5. Prevalence and change in prevalence of BSID (DASII) motor DQ below normal between 3–12 months

DISCUSSION

Discussion of birth outcome – preterm and low birth weight and neurological outcome

Studies similar to ours have reported that low birth weight and preterm birth were high-risk factors and an improved outcome was achieved after an intervention. In 2017, Zhang GQ *et al* (18) conducted a study regarding the neurodevelopmental outcome of preterm infants dis-

charged from NICU at one year of age and effects of intervention compliance on the neurodevelopmental outcome; the authors found that preterm infants discharged from NICU were a high-risk group of neurodevelopmental disablement; therefore, early intervention could improve their status.

Also, the study of MKC Nair *et al* (19) exploring the outcome at 12 months by the use of developmental assessment scale for Indian infants

found that LBW was a significant risk factor for poor development at one year of age.

Thus, LBW and preterm birth are significant high-risk factors for neurodevelopmental outcomes. Interventions give a better outcome in these factors for mental and motor development.

Discussion of Bayley's Scale of Infant Development to assess neurodevelopmental outcome

Other studies about BSID and neurodevelopmental outcome reported findings similar to ours. Thus, the studies of Samantha Johnson *et al* (12) and Luttikhuisen dos Santos ES *et al* (13) found that the neurodevelopmental delay classified using MDI scores <70 cut-off was used for outcome measure.

Soo A Kim *et al* (10) reported that BSID has long been considered the standard criteria for the developmental assessment of infants and subsequent diagnosis of cognitive-motor delays and BSID should be used as proper tools during the first year of life.

In their study, Michele A Lobo *et al* (20) found the effectiveness of BSID to track development and classified delays in low- and high-risk infants across the first two years of life.

Thus, in correlation to the above studies, the present study found that BSID (DASII) helped to assess mental and motor development and its predictive value of neurodevelopmental outcome at three months.

Discussion of neurodevelopmental outcome: hearing and vision

Motor and mental DQ of subjects with deafness and blindness were less affected by the admi-

nistered interventions compared to other high-risk neonatal diagnoses.

Study limitations

The sample was selected from a single institute. This research was not designed to study long term outcomes, the cohort was followed up only until children reached the age of one year, and the effect of medicine on development was not studied. □

CONCLUSION

Motor and mental DQ of deafness and blindness were less affected by the interventions compared to other high-risk neonatal diagnoses. Developmental assessment at three months using the DASII scale has a predictive value and helps plan early intervention. The present study has shown an improvement of neurodevelopmental outcomes in high-risk newborns at one year after applying two simple, home-based Indian Standardized Stimulation Programs. In addition, both stimulation programs considered the mother as a therapist, which lead to a reduced need for special therapies. □

KEY MESSAGES

Known facts – High-risk babies need developmental assessment and regular follow up.

What this study adds – Indian standardized stimulation programs given since birth considering mother as therapist improve the developmental outcome of high-risk newborns.

Conflicts of interest: none declared.

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