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COMPARATIVE STUDY TO ASSESS THE EFFECT OF LADDER APPROACH VERSUS KANGAROO MOTHER CARE ON NEURODEVELOPMENTAL STATUS IN SMALL FOR GESTATIONAL AGE PRETERM INFANTS.

Neonatology

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ABSTRACT

Some infants are born as Small for Gestational Age infants. Small for Gestational Age (SGA) preterm infants need special care ,as they are at the risk of infection, hypothermia etc. The early birth leads to lack of normal sensory experiences. This can lead to neurodevelopmental delay. Conventional care has shown the positive effects on development of SGA infants. Ladder approach ,allows the therapist to deliver sensory stimulations as per sensory system development. The study was designed to analyse the effect of Ladder Approach as compared to conventional preterm care consisting of Kangaroo mother care on neurodevelopment of preterm Small for Gestational Age Infants.

The Prospective Block Randomized study was conducted on 140 infants, assigned in two groups (70 in each group) with infants receiving conventional care & receiving Ladder approach respectively. Infants were assessed on Infant Neurological International Battery (INFANIB) and Developmental Assessment Scale of Indian Infants (DASII)at the end of 4 & 8 weeks. Significance Difference in all the Follow ups of INFANIB. There was increase in INFANIB score & on motor , mental scores of DASII in experimental group with 'p' ≤ 0.001 on last follow-up.

As Ladder approach considers the clues from preterm infants, the graded & need based therapy can be useful for achieving neurodevelopment & on the tonal maturation in preterm infants. The use of exogeneous and endogenous stimulation at appropriate time has resulted into long term neurodevelopmental improvement on Bayley scale of infant development. LADDER approach is comprehensive approach used in SGA preterm infants may show long term positive effects.

KEYWORDS

INTRODUCTION

Gestation is the period of time between conception and birth, A normal pregnancy can range from 38 weeks to 42 weeks. Infants born before 37 weeks are considered Preterm[1]. Preterm labor is any labor that occurs from 20 weeks through 36 weeks of pregnancy.-Some infants are born as Small for Gestational Age infants. Small for Gestational Age (SGA) infants are defined as having a birth weight less than 2 SD below the mean or less than 10th percentile for the gestational age.[2]

The adverse effects on preterm SGA infants can lead to delay in physical, Mental, Cognitive & Psychological development. Infants born SGA are at increased risk for a range of adverse physical and developmental outcomes.[3] This can be prevented using various therapeutic special care approaches. However Preterm with SGA babies needs special care as they are at a risk of complications. They lack prenatal sensory experiences due to preterm birth. This can lead to neurodevelopmental delay.

Kangaroo care has received favorable recognition as a new infant care technique. Typically, premature infants who have reached physiologic stability and who no longer need major respiratory support are put on their mother's chest (ideally in between the chest) in the fashion that allows for continuous skin to skin contact and facilitates thermal stability. The conventional care of preterm infants includes proper positioning, Kangaroo Mother Care, swaddling, splintage if required , thermoregulation , massage etc.[4]

Newborn Individualized Developmental Care (NIDCAP), is a program aims at decreasing the mortality rates for preterm newborns and newborns otherwise at high risk for developmental compromise & has proved to be neurodevelopmentally Supportive, individualized, and family-centered framework.[5, 6] Ladder Approach is based on NIDCAP framework. The ladder approach allows therapists to deliver treatment according to sensory system development, in a unimodal approach (until ready for multimodal stimulation), and at the right time in the infant's development.[7]The study was designed to analyse the effect of Ladder Approach as compared to conventional preterm care consisting of Kangaroo mother care on neurodevelopment of preterm Small for Gestational Age Infants.

METHODS

The study was Prospective Block Randomized study conducted in the Occupational Therapy department. Institutional ethics permission was taken. Permission was sought from the Neonatology unit of the institute. Study was conducted for one & half year in premature care unit & later in outpatient Occupational therapy department.

Infants meeting inclusion criterion -Age: 32-36weeks of gestational age, Small for gestational age infants were included in the study & infants with unstable vitals, congenital anomalies were excluded .

Infants were enrolled at the beginning of second week after birth.

Total 140 infants were recruited in two groups using block Randomization into Group receiving Kangaroo Care & another group receiving LADDER approach (70 in each group),in second week of their life.

The infants were first evaluated on outcome measures as INFANIB & DASII. Infants from experimental group received treatment using LADDER Approach for 30 minutes per day for first 7 days. Then the caregiver were trained (under supervision of therapist) to follow the same till infant completed 40 weeks of gestational Age (i.e. Term Age of Infants).

The ladder proceeds using sensory stimulus from bottom to up in the following manner as follows,Tactile / Proprioceptive,Vestibular, Olfactory / Gustatory, Auditory.

Infants were first given unimodal stimulus, as they were able to tolerate the various stimulus, they were gradually shifted to multimodal stimulus using the above mentioned sensory systems,as follows (Figure 1).

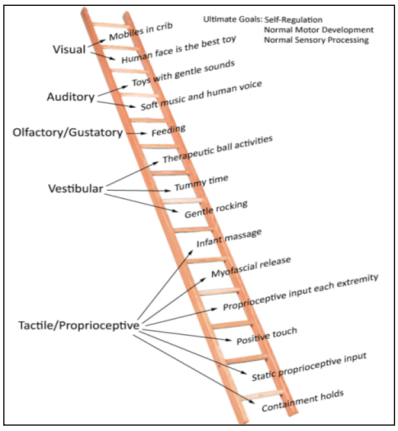

Figure1: Sensory ladder used in the LADDER approach

Infants from control group received Kangaroo Mother Care from mother/caregiver daily for minimum 6 hours per day. Caregivers were also taught Therapeutic positioning, therapeutic handling, tactile stimulations, Multimodal stimulations randomly along with handling techniques along with Kangaroo Mother Care training.

The neurodevelopmental status was assessed using Infant Neurological International Battery (INFANIB)[8,9] and Developmental Assessment Scale of Indian Infants (DASII)[10,11] were used as outcome measures at baseline,4 weeks & 8 weeks of term age. One of the investigators was trained for administration of DASII. The data was analysed using SPSS16.

Further Data was analysed using following Statistical test
Repeated measures ANOVA test was used for comparison of mean scores of DASII scores & INFANIB within group

Bonferroni *test* – is used for post hoc comparison between the groups was used for statistical analysis.

The p value less than 0.05 was taken as statistically significant.
The mean gestational age of infants in experimental & control group was 33.10 weeks & 33.14 weeks respectively. There were 38 male & 32 female infants in experimental group and 40 male & 30 female infants in control group.

INFANIB & DASII was used to assess the neurodevelopmental status of Infants. Assessment on INFANIB & DASII was done at baseline, 4th week term age & further follow-up at 8th week.

Table: 1 Shows among the group comparison of INFANIB scores in Infants in all the follow ups.

Group	INFANIB	N	Mean	SD	P value	Significance
Experimental Group	Baseline	68	52.35	3.40	-----	-----
	4 wks	68	55.72	3.44	<0.001	Significant
	8 wks	68	61.99	4.20	<0.001	Significant
Control Group	Baseline	64	51.22	2.75	-----	-----
	4 wks	64	54.42	3.00	<0.001	Significant
	8 wks	64	58.83	3.82	<0.001	Significant

(Repeated measures ANOVA with Bonferroni Post hoc test) (P significant if 'p' ≤ 0.05) Shows Significance Difference in all the Follow ups of INFANIB. As seen in

Table 1 increase in INFANIB score in experimental group (C.I. - 61 to 63) was more than control group (55 to 61).Further the improvement in the score during each follow-up was compared.

Table: 2 shows comparison in improvement of INFANIB scores between both the groups during each follow up.

INFANIB	Group	N	Mean	Std. Deviation	P value	Significance
Difference (Baseline & 4 weeks)	Experimental	68	3.37	2.30	.734*	Not significant
	Control	64	3.20	1.79		
Difference (Baseline & 8 wks)	Experimental	68	9.63	3.56	<0.001 *	Significant
	Control	64	7.61	3.23		

(*Mann Whitney U test)(P significant if 'p'≤0.05)

During first follow up the difference in improvement between two groups is observed to be non Significant but significant difference was observed at 2nd follow-up.

Later the data on Motor & Mental development quotient using Developmental Assessment Scale for Indian Infants (DASII) was analysed.

Table: 3 Shows comparison of Motor Quotient & Mental Quotient on DASII scores in Infants among the group in all the follow ups.

Group	Motor Quotient	N	Mean	SD	P value	Significance
Experimental	Baseline	68	67.06	7.55	-----	-----
	4 wks	68	67.06	11.34	1.000	Not significant
	8 wks	68	78.31	15.99	<0.001	Significant
Control	Baseline	64	65.12	7.70	-----	-----
	4 wks	64	61.94	7.90	0.028	Significant
	8 wks	64	70.34	10.98	<0.001	Significant
	Mental Quotient					
Experimental	Baseline	68	69.09	9.94	-----	-----
	4 wks	68	72.88	10.20	0.127	Not significant
	8 wks	68	84.14	14.96	<0.001	Significant
Control	Baseline	64	66.76	6.95	-----	-----
	4 wks	64	67.50	8.57	0.048	Significant
	8 wks	64	74.49	14.01	<0.001	Significant

(Repeated measures ANOVA with Bonferroni Post hoc test)
(P significant if 'p'≤0.05)

There was no significant difference in first follow up in Experimental group in Motor Quotient but showed significant difference in all the next follow-ups for both the groups. Increase in DASII score in experimental group i.e group1 (C.I. --76 to 84) was more than control group i.e group 2(C.I. -- 68 to 72).

In Mental Quotient no significant difference obtained at 1st follow up in Experimental group but showed significant difference in all the next follow-ups for both the Groups. The difference in improvement in score in the groups was compared later.

Table: 4 Shows comparison in improvement in Scores on Motor Quotient & Mental quotient scores of DASII in both the groups during each follow up.

DASII (Motor Quotient)	Group	N	Mean	Std. Deviation	P value	Significance
Difference (Baseline& 4wks)	Experimental	68	0.00	10.78	.136*	Not significant
	Control	64	-3.18	9.49		
Difference (Baseline &8 wks)	Experimental	68	11.26	15.18	.029*	Significant
	Control	64	5.21	10.18		
DASII (Mental Quotient)						
Difference (Baseline&4 wks)	Experimental	68	3.79	15.11	.857*	Not significant
	Control	64	3.10	8.73		
Difference (Baseline&8 wks)	Experimental	68	15.04	17.41	.005*	Significant
	Control	64	10.08	13.68		

(*Mann Whitney U test) (P significant if 'p'≤0.05)

Non-Significant Difference was observed at 1st follow up from Baseline but significant difference was observed at 2nd follow up. The mental quotient were considered later. There was no significant difference between two groups in the scores of improvement between baseline & 1st follow, but Significant difference was observed at 2nd follow up.

DISCUSSION

This study included 140 subjects. Control group was given Kangaroo Mother Care with conventional preterm care and Experimental Group received Ladder Approach, based on the recent updates in Developmental Care Intervention for Preterm Low Birth Weight Infants. Infants in both the groups were matched for their gestational age. The effect of intervention was measured using INFANIB & DASII. When compared the scores on INFANIB, both the groups showed significant difference in each follow up. In a review conducted on effect of KMC on neurodevelopmental outcome in preterm infant in Journal of Perinatal it reported lower number of arousal while in KMC, it reported organized sleep pattern improving Autonomic Nervous

System. This has resulted in long term positive effects on Cognitive improvement as well.[12] Both the intervention showed significant difference during the follow up in the scores of Motor System with p value ≤ 0.001.Motor development as assessed in INFANIB has shown the definite improvement in both the groups, but better improvement in infants receiving LADDER approach at 8th week. The increase in INFANIB score in experimental group (C.I. - 61 to 63) was more than control group (C.I-55 to 61). As seen in table 2 difference in improvement between baseline score and second follow-up score is significant. In ladder approach one of the rung includes proprioceptive stimulations & Infant massage which may have improved motor system of these infants. In the systematic review on "The effects of massage therapy in hospitalized preterm neonates by Álvarez MJ, et al" total of 23 articles were included, the results stated that benefits included increased vagal activity, increased gastric activity and increased serum insulin levels. With benefits to hospitalized preterm infants included better neurodevelopment, a positive effect on brain development.[13]

In one more study conducted by Dr.Anjali Kulkarni , the review suggested that massage has several positive effects in terms of weight gain, better sleep-wake pattern, enhanced neuromotor development, better emotional bonding, reduced rates of nosocomial infection and thereby, reduced mortality in the hospitalized patients.[14]The Ladder approach recommends gradual administration of unimodal to multimodal stimulations in preterm infants. In one of the article on 'Effect of multisensory stimulation on neuromotor development in preterm infants, it was stated that multimodal stimulations leads to better neurobehavioral response if auditory, tactile & vestibular stimulations are used with gradations.[15] Thus the overall effect of multimodal stimulations has seen after preterm infants started receiving higher level stimulations. As stated in the NIDCAP approach individual's responses from infants can guide the therapist for going for more complex stimulations. As Ladder approach considers the clues from preterm infants, the graded & need based therapy can be useful for achieving neurodevelopment.[7] Multisensory stimulation appears to have a beneficial effect on the tonal maturation in preterm infants. There is scarce literature on the long-term effect of multimodal stimulation on neurodevelopmental outcome in preterm infants. When improvement between the two groups was analysed between baseline, First follow up & second follow up, increase in INFANIB score in experimental group i.e. group1(C.I. - 61 to 63) was more than control group i.e. group 2(55 to 61). In present study the ladder approach consisted of gradual administration of multimodal stimulus.

In another study on the Effects of early multimodal stimulation on preterm newborn infants, the author had administered multimodal stimulation consisted of auditory, tactile, kinesthetic stimulations on nine neonates with the gestational age less than or equal to 34 weeks, the effect on neurobehavioral performance and postural reflexes were significant in the study group.[16]

Another outcome measure i.e. Developmental Assessment Scale For Indian Infants (DASII) was used to assess Motor & Mental development quotient. There was no significant difference in first follow up in Experimental group ,but showed significant difference in the next follow-ups for both the groups. KMC is also useful for stimulating motor development. This goes in accordance with control clinical trial on Low birth weight Babies treated with KMC by Bera A. The author included 500 low birth weight infants in her study and observed that infants in KMC group surpassed the babies in conventional group in DASII motor and mental developmental quotient.[17]

The statistically significant difference was evident with the vast difference during last follow-up in the scores of motor quotient. It implies that administration of Ladder approach with multimodal gradual sensory stimulation was more effective than KMC in long term effects of intervention. In the second follow up experimental group i.e group receiving LADDER approach (C.I.76 to 84) was more than control group i.e. group 2(68 to 72).In experimental group the infants received need based treatment, as per each infant's response as recommended in Ladder approach. In the review on Development of potentially better practices to support the neuro development of infants in the NICU, the authors have evidence of environmentally based approach thus recommending 'bundle approach' with multimodal exogenous exposures to various stimulus. In this systemic reviews of clinical trials brought developmental care interventions authors have recommended comprehensive approach for developmental care and individualized developmental care (NIDCAP) has related better sleep pattern and overlapping beneficial effects on the development of the infants. The use of exogeneous and endogenous stimulation at appropriate time has resulted into long term neurodevelopmental improvement on Bayley scale of infant development.[18]

In this study, in experimental group the infant's responses to various stimuli were observed and intervention was individualized as per infant's responses. This intervention was mainly based on the principles of NIDCAP.[5,6]

Further the infants in this study showed gradual progress Mental scores on DASII from the beginning. In a study on' Kangaroo Mother Care: A method for protecting high risk low birth weight premature infants against developmental delay', 431 infants receiving KMC in the study showed higher IQ on Griffith score as compared to traditional care group infants the authors have concluded that KMC provides "Brain care" during highly sensitive period of preterm infant neurological development.[19]

When compared between the groups difference in the improvement was statistically significant. Infants receiving LADDER approach showed significant difference i.e improvement in mental score than infants receiving conventional care. Ladder approach has used multimodal stimulations effectively; this may have led to better arousal & cognitive stimulations. In the study to analyse effect of multimodal stimulation on arousal of infants, authors have concluded that tactile stimulation alone may be too arousing for these infants while the addition of vestibular stimulation may modulate arousal and facilitate optimal arousal prior to feeding & better receptive ability of infants, with better state organization. In the present study this may have helped in improving neural networks.[20] In the study of ' Effect of Early Multimodal stimulation on preterm newborn infants behaviours' stated that during last trimester of pregnancy preterm newborn are deprived of both maternal biorhythms, tactile kinesthetic and Auditory stimulation which characterize the intrauterine environment . In the study 9 neonates were given multimodal stimulation program.During the follow up of the study.It was observed that there was statistically significant difference in Neurobehavioral performance and postural difference in the study group.[16]

The tummy time and containment hold in Ladder Approach may have improved Interactive Skills.[21] In an article on need of positive touch, it was stated that Over 600 scientific papers have been published on the effects of human touch on babies. Babies have an innate need to be loved and nurtured and develop trust and attachment. Studies of babies (human and animal) in suboptimal conditions (e.g., orphaned infants, infants separated from their mothers) have shown the striking negative impact from separation from caregiver.[22]

In addition to this Ladder approach recommends the education of parents/ caregivers about use of different unimodal /multimodal stimulations during intervention. Thus the context focused & family centered ladder approach based on NIDCAP principle, has given better results than conventional KMC approach. In the study conducted on 156 premature infants to analyse 'The effect of Family centered Physiotherapy on the cognitive and motor performance in premature infants', authors have observed that cognitive development scores have significantly improved with p = 0.059, thus supporting the comprehensive approach.[23] In our study Ladder approach considers multimodal stimulations, parents preferences & environmental conditions.

This study was conducted in the Neonatal intensive care unit & premature care unit of the hospital. Some sensory inputs like sounds of equipment, monitors, handling of infants by other paramedical staff for child care etc. could not be controlled completely. This may have affected the results in the study. It was tried to minimize by explaining the paramedical staff about importance of minimal handling and reducing the sounds of equipment to minimal level. The study was blinded only for the caregivers / parents. The researcher has administered the intervention & done assessment on outcome measures. Though the researcher was conscious about avoiding the bias. Human error in this case cannot be negated. The results in present study have shown statistically significant difference in improvement scores of infants receiving LADDER approach as compared to infants receiving conventional treatment on INFANIB & DASII. Intervention

using Ladder approach guide the systematic administration of various stimulus leading from unimodal to multimodal stimulation. The outcome measures used in the study were related to developmentally appropriate daily activities, parents could get better insight about infants' progress. The study was on small sample size & sociocultural factors were not considered while administering & comparing on Motor & mental development. This may have had impact on the development of infants after discharge. Comparison of effect of Unimodal sensory stimulation approach with multimodal stimulation approach on SGA infants & further study on premature infants with the different Co-morbidities are recommended

CONCLUSION

Infancy is the period of rapid psychomotor, cognitive, and social development. The first month of life is a critical period in an infant's life as its major adaptation to extra uterine life occurs. The in-utero early sensory experiences of the fetus are essential for normal brain development during the perinatal period. Medical advances and improvement of care for infants in the NICU have led to higher chance of survival of these infants compared to premature infants born before these years. Despite their higher chance of survival, the likeliness of disturbances in their nervous system development has increased. The premature infant (considered as extra-uterine fetus) is deprived of in-utero sensory experiences, rather exposed to unusual sensory stimuli in the Neonatal Intensive Care Units (NICU) that pose risk to the developing brain in terms of adverse neuro-developmental outcomes. The Developmental Care Interventions (DCI) are essential to minimize the risk thereby improving neurodevelopmental outcomes. Infants born SGA are at increased risk for a range of adverse physical and developmental outcomes, caregiver responsiveness. This enhances more mature responses from the central nervous system & thus leading to better mental & motor development LADDER approach is comprehensive approach used in SGA preterm infants may show long term positive effects.

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