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The Effect of Pre-Feeding Protocol with and Without Tactile and Kinaesthetic Stimulation on Oral Motor Ability & Neurodevelopmental status of Preterm infants

Dr Shailaja S.Jaywant[1], Dr Jayashri S.Kale[2]
[1]*Assistant Professor,Occupational Therapy Department,L.T.M.M.college &G.Hospital,Sion,Mumbai*
[2]*Prof& Ex HOD ,Occupational Therapy Department ,Seth G.S Medical College & KEMH,Parel,Mumbai*
(Corresponding Author)

Abstract
Background*-Preterm infants often have feeding difficulties lead to morbidity or developmental co-morbidities.PIOMI with Kinesthetic respiratory muscle stimulation has been shown to achieve better physiological stability.Study was planned to analyse effect of this combined protocol on achieving oral motor control and Neurodevelopment as a long term effect.*
Methodology*-A total 113 clinically stable infants from premature care unit, fulfilling inclusion criterion were enrolled. They were allocated in Infants receiving PIOMI (Control group) and infants receiving the new intervention protocol i.e. PIOMI with M technique, Respiratory muscle stimulation (Experimental group), for 10 minutes each day. Data was collected for oral motor abilities, day of achieving full feeds & Later Neurodevelopmental status after 6 months .*
Results*-Mean age of achieving full feed had differed by 9.77 days with p=0.000 .Difference in NOMAS score on 8 day was 3.345 with 'p'= 0.000. INFANIB score at the end of 6 months ,78.1% &3.1%infants achieved normal score from experimental & control group respectively,with'p' =0.000*
Conclusion*-New intervention protocol i.e. PIOMI with M technique, Respiratory muscle stimulation was well tolerated by preterm infants. This led to achieving early oral feeds & resulting in better Neurodevelopmental status*
Key words—Preterm Infants, NOMAS, respiratory muscles, Neurodevelopment

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I. Introduction

The high prevalence of preterm births 1out of 100 live births in India ,leads us to consider various problems faced by preterm infants to prevent the morbidities. In very preterm infants before 34 weeks of gestational age it is necessary to use a feeding tube, depriving normal sensory stimuli,& thus hinders its oral-motor development,which in turn alters the sucking-swallowing-respiration coordination in preterm infants.This impairs the oral feeding even more . This leads to poorer feeding performance, prolonging duration of hospitalization in the neonatal unit. [1]The development of feeding pattern depends upon brainstem central pattern generators whose activity is increasingly influenced by chemosensory and oral tactile input.This further influences the neurobehavioural status & later the neurodevelopmental status of preterm infants.

Various oral motor stimulation programs that are designed before involve tasks such as stroking the peri-oral and intraoral structures in a specific way with a gloved finger for a period of time prior to feeding. [2]

Brenda Lesson had shown the early feeding transition using Premature Infants oral Motor Intervention technique. [3] Dr Karan et al has proved that infants receiving PIOMI reached full independent wati spoon feeds earlier than the infants in control group with the significant difference in number of days. [4]

Several swallowing muscles in the mouth, pharynx, and larynx exhibit either an inspiratory or an expiratory activity. The coordinated activity in oro-pharyngo-laryngeal muscles ensures the patency of the upper airway and regulates the airflow during the respiratory cycle. Adductor muscles of the larynx are active during the expiratory phase of the respiratory cycle and regulate the rate of airflow during expiration, whereas abductor muscles become active during inspiration, thus ensuring airway patency, [5]

Vibratory stimuli applied to the chest wall of preterm infants can cause significant changes in the pattern of breathing. The stimulation of somatosensory afferents might be pleasurable, and promote the stability of breathing in neonates. Somatic stimuli facilitate breathing and attenuate inhibitory reflexes. [6]

Suck swallow breathe are all connected to the lung pressures a graduated proprioceptive stimulation to the intercostal, coordinating to the phases of breathing may enhance the process of Nutritive Sucking. The

new technique incorporating concepts of tactile Kinesthetic &respiratory muscle stimulations that can enhance neurobehavioral organization with suck swallow breath rhythm& later may result in better neurodevelopment in preterm infants.

This study intends to analyse effect of the new oral motor intervention protocol on achieving oral motor skills & later improving neurodevelopmental status of preterm infants.

II. Material & Methods

The study was experimental , prospective with random allocation of subjects, triple blinded, analytical study. Infants were recruited from a premature unit under department of neonatology at a tertiary care hospital in metropolitan city.

All Infants admitted in the premature unit. Infants born between 28.0/7 and 32.0/7 weeks of gestation, clinically stable as per the medical staff at the time of entry. Infants were on only orogastric or Nasogastric Feeds, few infants needed oxygen supply for initial 3-4 days due to low gestational age , infants with NOMAS score between 18-36 were included. Breast milk of the mother was used, when available. If unavailable, donated human milk from milk bank was used for their feedings. Infants with congenital anomalies, neonatal asphyxia defined by a 5th min Apgar score of 6 or less. Grade III or IV intracranial or intra ventricular haemorrhage, meningitis/sepsis, neonates with mechanical life support, infants with necrotizing enterocolitis (NEC) were excluded. The study was approved by institutional ethics committee.

A convenient sampling with random allocation was done in control and experimental group, by using block of 6 subjects, to allow equal distribution in both the groups and thus forming three sets of infants in each block. The sample size decided was 53+ 5 (Considering dropout rate)in each group, as per the effect size(On days to achieve full feeds) following the pilot study in premature care unit and neonatal intensive care unit. Intervention was started using two different protocols as per intervention groups. The informed consent was obtained from caregivers and they were explained about the benefits. They were assured about precautions taken while handling the infants.

Control group received protocol A, experimental Group received protocol B, Initially 58 infants were included in each Group.Three infants had dropped out from control group.

All the infants from the two groups received intervention for minimum 8 days or till they received full oral feeds (if oral feeding achieved earlier), thirty minutes prior to feeding. The infants from Control group received PIOMI for 10 minutes, at least once a day. Infants from experimental Group received M technique consisted of series of massage on trunk and extremities for 3.5minutes followed by PIOMI for 5 minutes + respiratory muscle stimulation 1.5 minutes, once a day.Intervention was provided by two research assistants (RA), both were given the training for different protocols. For blinding the groups, the curtain was pulled between each isolate in preterm unit. Intervention was given at least once a day by the therapist and this was separated by a minimum of nine hours and a maximum period of 36hours. Variations were considered, as sometimes the infant had been stressed by medical or nursing procedures such as intravenous infusions or temperature instability immediately before the scheduled time of intervention. Negative neuro-behavioural cues were also recorded during the intervention. For both the groups assessment was done at baseline i.e.day 1,Day4 & Day 8 of intervention on NOMAS scale ,day of achieving full feed was recorded for each infant ,with record of days of hospital stay.The infants were followed up in the first week after completing corrected age of six months .They were assessed using INFANIB(Infant Neurological International Battery) for assessing Neurological Integrity in Infants. The principle investigator was blinded for the type of intervention used for the patient. Confounding factors such as feeding protocol by nursing staff experienced in preterm infant feeding and inexperienced parent feeder were not recorded .Two infants from control group dropped out from study as they developed NEC during the protocol and took AMA discharge.

Statistical Analysis

SPSS-PC 16.0 (IBM, Somers, New York) was used for all analysis. Preliminary data analysis was done using descriptive statistics. The α was set at 0.05 (1-tailed). Demographics were also recorded to analyse the group differences for, ordinal data i.e., age of enrolment, days for full feeds, length of hospital stay was analysed using mann whitney U test. The nominal data were tested with chi square x2 values. Data was compared using Kruskal Wallis score. INFANIB Scores were analysed on contingency tables or using cross tabs.

116 preterm infants were enrolled in each group, 2 mothers took discharge against medical advice from control group. one infant from control group expired after discharge, so their data was excluded from initial analysis. Thus total 113 infants were analysed at end of the study. Fifty five infants from control group & fifty eight from experimental group were included on last day analysis.

III. Results

Table 1 shows both the groups has gestational age between 28 weeks to 31 weeks. Enrolment was done at 32 weeks PMA.

Table1:- Shows the Gestational age at enrolment & duration of hospital stay

Dependant Variables	Group	N	Mean	Std.Dev	Std.Error	95%cofidence Interval		Significance 'p'
						Lower bound	Upper Bound	
Gestationl Age at enrollment	Control	55	30.4309	1.52605	0.20577	30.0184	30.8435	0.399
	Experimental	58	30.8414	1.40987	0.18512	30.4707	31.2121	
Days of full feeds	Control	55	19.7273	4.73542	0.63852	18.4471	21.0074	0.000*
	Experimental	58	9.9483	2.80615	0.36847	9.2104	10.6861	
Days of Hospital Stay	Control	55	24.9455	5.92364	0.79871	23.3341	26.5468	0.000*
	Experimental	58	15.810	5.42074	0.71178	14.3850	17.2357	

'p'Significant if 'p'≤0.05

There was significant difference in age of achieving full oral feeds (i.e. at least 8 oral feeds in 24 hours)The infants receiving new protocol achieved full oral feeds 9.8 days earlier than infants receiving PIOMI('p '≤0.000). There was statistically significant ('p'≤0.005) reduction duration of hospital stay in infants receiving new protocol by 9.13 days.('p'=0.000),using Mann Whitney U Test

Further data was analysed to compare the oral motor abilities in infants receiving two different interventions using NOMAS scale .It is analysed using NOMAS Jaw score ,NOMAS tongue score & overall NOMAS score

Table2 :Shows NOMAS Jaw score at each followup in both the groups

followups	Group	N	Mean	Std.Dev	Std.Error	95%cofidence Interval		Significance 'p'
						Lower bound	Upper Bound	
Day1	Control	55	13.0182	1.8806	0.254	12.517	13.520	0.261
	Experimental	58	13.6364	1.9660	0.254	13.135	14.318	
Day4	Control	55	14.2909	2.0518	0.280	13.738	16.592	0.011
	Experimental	58	15.4545	1.7828	0.280	14.902	14.007	
Day8	Control	55	15.9636	2.2275	0.318	15.335	16.592	0.001
	Experimental	58	17.6080	2.3374	0.318	16.972	18.228	

'p'Significant if 'p'≤0.05

Then oral motor ability /skills were analysed using NOMAS score , as seen in Table 2. Since the data is ordinal data, pair wise multiple comparison as done. The scores were analysed separately for the Jaw and the Tongue. Then NOMAS Tongue score was analysed

Table 3 :Shows NOMAS Tongue score at each folloup in both the groups

Followups	Group	N	Mean	Std.Dev	Std.Error	95%cofidence Interval		Significance 'p'
						Lower bound	Upper Bound	
Day1	Control	55	14.1091	2.5820	0.324	13.469	14.749	1.000
	Experimental	58	14.0364	2.3251	0.324	13.396	14.676	
Day4	Control	55	15.3455	2.2788	0.318	14.717	15.974	0.032*
	Experimental	58	16.5091	2.4711	0.318	15.880	17.138	
Day8	Control	55	17.2364	2.4492	0.329	16.588	17.885	0.001*
	Experimental	58	18.9455	2.5196	0.329	18.297	19.594	

'p' Significant if 'p'≤0.05

Pairwise comparison(Mann Whitney U test) was done . The significant difference in mean score of NOMAS jaw score was observed during both the follow ups i.e. on the 4th day('p'=0.011) (mean score14.291 & 15.455)

in control & experimental group respectively and on the 8th day('p'=0.001) (mean score15.964&17.600 in control & experimental group respectively) . Infants from experimental group showed much higher mean score than control group subjects on jaw score during each follow up. Similar trend as observed in tongue score as on day 4 ('p'=0.032)& on day8 significant difference was with 'p'=0.001.
Further overall NOMAS score was analysed

Table 4:- Shows NOMAS Total score at each follow up in both the groups

Follw ups	Group	N	Mean	Std.Dev	Std.Error	95%cofidence Interval		Significance 'p'
						Lower bound	Upper Bound	
Day1	Control	55	27.1273	3.9207	0.495	26.150	28.105	1.000
	Experimental	58	27.6727	3.6617	0.495	26.695	28.650	
Day4	Control	55	29.6364	4.0201	0.556	28.539	30.734	0.011
	Experimental	58	31.9636	4.2173	0.556	32.866	33.061	
Day8	Control	55	33.2001	4.5817	0.595	32.025	34.375	0.000
	Experimental	58	36.5455	4.6808	0.595	35.370	37.721	

'p' Significant if 'p'≤0.05

The overall scores of NOMAS were compared to find the overall ability of infants at each follow-up. .In these scores preterm infants from experimental group showed higher mean 31.964& 36.540 at both follow-ups ,as compared to control group with score as 29.636 & 33.200 at two follow ups with statistical significance 'p'=0.011 & 'p'=0.000 on day 4 & day 8 follow up respectively.
Further INFANIB score was analysed to evaluate effect of multisensory stimulations given as oral motor stimulation protocol on the neurodevelopmental status of preterm infants , after completing 6 months of corrected age .INFANIB is categorised as Abnormal, Transient & Normal scores. At 4-6 months if score≤54 = Abnormal, if score between 55to 71= Transient & if score ≥71 = Normal
Since the data was categorical, Data was further analysed using Cross tabulation table/Contingency table.

Table 6 shows INFANIB score in both the groups at completion of 6 months

Dependant Variable			**Control Group**	**Experimental Group**	**Total**
INFANIB	Abnormal	Count	17	08	25
		% Within group	30.9%	13.8%	22.3%
		% Residual	6.9%	2.7%	
	Transient	Count	37	25	62
		% Within group	67.3%	43.1%	55.2%
		% Residual	2.6%	- 11.6%	
	Normal	Count	1	25	26
		% Within group	1.8%	78.1%	39.6%
		% Residual	- 9.5%	14%	

There is residual of 6.2 in abnormal group from group receiving PIOMI ,means this group had more than expected number of infants , group receiving MIOMI & Respiratory stimulation had negative residuals equals to -2.7 showing less than expected number of infants showing abnormal development as per INFANIB

There is positive residual values seen in transient development in infants receiving PIOMI showing more number of infants in transient developmental level than expected ,where as infants receiving MIOMI +Respiratory stimulations have residual value -11.2showing ,much lesser than expected number of infants in this group .In control group30.9% infants showed abnormal development score ,whereas 13.8% infants from experimental group had abnormal scores. In Control group 67.3% infants & in experimental group 43.1% were in transient stage of development .Normal developmental scores were observed in1.8% &78.1% 0f infants in control & experimental group respectively

Thus better developmental level i.e .Normal development level in the group of infants receiving MIOMI + Respiratory stimulation with residual value +14.00 and group receiving one PIOMI showed negative residual values indicating the less number of infants showing expected normal development.

Thus infants from control group could reach to transient developmental stage, but percentage of expected population to achieve normal development remained low as compared to experimental group.

IV. Discussion

The study was designed to determine the effect of the new intervention protocol, on preterm infants to enhance oral motor performance, achieving full feeds, length of hospital stay and the ong term effect on neurodevelopment of these infants. Pre-feeding stimulation in preterm infants reduces transition from gavage feeding to oral feeding and reduces duration of hospital stay. [7] [4]

In this study with new protocol, the number of days from gavage feedings to oral feedings significantly reduced compared with the number of days for the infants who received only PIOMI intervention. The experimental group infants were able to achieve full feeding 9.13 days faster than infants from control group.In the new protocol infants received M technique along with the respiratory muscle stimulation & kinesthetic stimulation ,which may have enhanced the suck- swallow-breath coordination. The perioral & intraoral stimulation with oral support in the form of stimulation on the chin to pharyngeal muscle to help in deglutition can help in enhancing the swallowing .as seen in the study done by Boiron et al, the oral stimulation consisted of 12 minutes of stimulation delivered once a day, 30 minutes before gavage feeding, significant difference for sucking activity at D17 for the Stimulation+ oral support group compared with the control group. They explained by the high density of sensorial receptors in the buccal areas involved in these perioral and oral manuvers. Authors stated that oral support protocol can be considered as training for endurance and coordination because the therapist organizes the sucking–swallowing -breathing sequence during feeding [8]

As proposed by Steven Barlow ,Functional linkages between suck–swallow and swallow–respiration manifest transitional forms during late gestation and can be delayed or modified by sensory experience and/or disease processes. Central pattern generator (CPG) networks in brainstem and their neuromuscular targets attain functional status at different rates. This may differ in each individual as per their experiences . He proposed Entrainment of trigeminal primary afferents to activate the suck CPG as clinical intervention. [9]]The perioral stimulations with the stimulations on pharyngeal muscles in the new protocol may have enhanced the suck swallow breath coordination to improve feeding ability of preterm infants.

In another study done by Sandra Ficile, it was evident that the infants receiving oral stimulation along with tactile & kinaesthetic stimulation develop good expiration -swallow -expiration cycle than infants receiving only oral stimulation, due to which , more infants showed feeding ability without apnoea ($p \leq 0.039$) [10]

Mechanical tactile stimulation has been evaluated in several studies .It was observed that these stimulations lead to a faster response to stabilise Heart rates & O2 saturation .In our pilot study done on the effect of pre-feeding protocol with and without tactile and Kinaesthetic stimulation on oral motor ability & physiological stability in preterm infants, it was stated that the location of stimulation also influences the effect on breathing& feeding coordination, leading to physiological stability. [11]]Thus this specifically designed protocol emphasizes to stimulate the target muscles

The early achievement of oral feeds with better suck swallow breath coordination, have also resulted in early discharge from the hospital.

Infants from experimental group also achieved better oral motor ability as seen on NOMAS Jaw , NOMAS tongue & Overall NOMAS score ,with significant difference on 8th day of intervention , resulting in early transition to oral feeding. When Bertoncelli N et al and others reviewed the effect of sensorimotor stimulation with oral stimulation, it revealed that oral and non-oral sensorimotor interventions when provided in combination ,leads to more advanced nutritive sucking, suck-swallow and swallow-respiration coordination than those who received an oral or sensorimotor intervention singly. [12]

Graded sensory stimulation was administered during the experimental protocol in preterm infants. This sensory stimulation protocol follows the early developmental care guidelines using tactile ,proprioceptive ,kineasthetic & olfactory stimulations in graded & controlled manner. These infants were assessed again after completing 6 months of corrected age to analyse the effect of early sensory stimulations & care they received during early phases of infancy .The preterm infants from experimental group showed significant difference in neurodevelopmental status ,78.1% infants showed normal development on INFANIB with p=0.000 as compared to control group.

In a systematic review and meta-analysis Effectiveness of interventions on early neurodevelopment of preterm infants, it was observed that compared to standard care, the NIDCAP intervention is effective in improving preterm infants' neurobehavioral and neurological development at two weeks PCA. For all other interventions (i.e., developmental care, sensory stimulation, music and physical therapy), the synthesis of results shows that compared to standard care or other types of comparators, the effectiveness was either controversial or partially effective. Authors have cautioned that Interventions should be appropriately designed to allow comparison with previous studies. [13]In a study on analysing the effect of early oral feeds achiever on further neurodevelopment ,it was observed that preterm infants who achieved full oral feeds at the end of 37 weeks CA ,showed age appropriate development at end of 18 & 24 months corrected age than preterm infant who achieved feeds later than 37 weeks CA. [13]

In another study on effect of multisensory stimulation on neuromotor development of preterm infants ,it was observed that at term age ,infants receiving multisensory stimulations consisted of Auditory, Tactile, Visual and Vestibular stimulus, Multisensory stimulation showed an immediate beneficial effect on the tonal maturation in preterm infants. Authors state that procedure should be an integral part of routine developmental care for healthy preterm infants. Authors have warranted further studies to investigate the long-term effects of multisensory stimulation on neurodevelopmental outcome in preterm infants. [14]

This study has tried investigating the long term effect of multisensory stimulations consisted of tactile, proprioceptive , kinesthetic, olfactory & vibratory stimulations.In an another study by Sandra fucile the researcher has predicted the effect of limited duration multisensory stimulation on the motor development of infants at 18 & 24 months ,stating that the duration of stimulation is important in achieving target & avoiding the synergistic effect. [15]

V. Conclusion

The combined effect of pre-feeding stimulation with M- technique & respiratory stimulation in new protocol has led to improved oral motor skills, improved feeding, leading to early hospital discharge and improved neurodevelopmental status. Although this study does not report morbidity levels more research is needed to determine both the short-and long-term benefits of the new protocol.

This is easy to learn, and relatively short in duration protocol. Training parents to do the intervention under supervision of the therapist had enhanced parent/infant interaction. The health care staff was advised to attend to infants when mother was giving stimulations. The caregiver was also trained for safe handling techniques. In this study the mothers and care givers skills for feeding the infants orally were not considered.
Future studies might be considered for other benefits such as, physiological stability, monitoring the other morbidities and in-depth observation of neurodevelopmental status in infants in as a long-term effect.

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