Prefeeding Oromotor Stimulation Program for Improving Oromotor Function in Preterm Infants – *A Randomized Controlled Trial*

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Objective: To determine effect of Premature Infant Oral Motor Intervention program on oro-motor function and time to full independent wati spoon feeds in preterm infants. **Methods:** 30 preterm infants between 28-32 weeks of gestation on full gavage feeds of 150 mL/kg/day were randomized to receive either pre-feed oro-motor stimulation using Premature Infant Oral Motor Intervention (structured stimulation) or sham intervention (unstructured stimulation). **Results:** Improvement in mean (SD) Neonatal Oro-Motor Assessment Scale (NOMAS) over 7 days from baseline was significantly higher in the study group infants as compared to control group (9.25 (1.73) *vs* 4.79 (1.52), *P*=0.001). Infants in the study group reached full independent *wati* spoon feeds significantly earlier than the infants in control group (4.0 (0.8) d; *vs* 6.64 (1.0) d; *P*=0.001). There was significant increase in weight gain after enrolment in infants in study group compared to those in control group. **Conclusions:** Oral stimulation program improves the oro-motor skills and growth velocity in 28-32 week preterm infants. There is decreased transition time from gavage to full independent feeds by mouth.

Keywords: *Breestfeeding, Neonate, Prematurity, Stimulation.*

Preterm infants less than 32 weeks are incapable of independent oral feeding and require gavage feeds for a variable period of time after birth. They frequently experience oral feeding difficulties due to underdeveloped oral motor skills and lack of coordination of sucking, swallowing and respiration [1,2]. Infant's ability to consume all feeds orally while maintaining physiologic stability and demonstrating weight gain is necessary prior to discharge [3]. Beckman Oral Motor Intervention (BOMI) is a 15-minute oral intervention for infants and children with developmental delays and feeding difficulties but is not suitable in preterm infants due to smaller oral cavity and longer administration time [4]. The Premature Infant Oral Motor Intervention (PIOMI) is a new intervention that is adapted from the BOMI to enhance the premature infant's ability to accept oral feeds [5]. The purpose of this study was to determine efficacy of PIOMI as measured by a shorter transition from gavage to full *wati* spoon feeds and shorter duration of hospital stay.

METHODS

This randomized controlled study was conducted in the neonatal unit of a tertiary care centre over 3 months from March-May 2014, following approval from our institutional ethics committee. All infants admitted to the unit and born between 28 to 32 weeks gestational age, once medically stable with no respiratory support for atleast 48 hours and on full gavage feeds of 150cc/kg/day, were eligible for enrollment into the study. Infants having respiratory distress and those with chronic medical complications like BPD, IVH, PVL, NEC, chromosomal anomalies or craniofacial malformation were excluded from the study. Written informed consent was taken prior to enrollment.

Infants meeting eligibility criteria were randomized to receive oro-motor stimulation using either Premature Infant Oro-Motor Intervention (PIOMI) or sham intervention. Randomization was done using a computer generated randomization sequence placed in sealed, opaque, sequentially numbered envelopes. The physician on call opened the sequentially numbered sealed opaque envelopes and randomized infants to the respective groups. The principal investigator underwent a training for this oro-motor intervention in the department of occupational therapy for 15 days prior to the start of the study regarding correct order of steps in the protocol with correct technique and time spent at each step. Intervention

in both the groups was done by the principal investigator and duration did not exceed 5 minutes in either group.

Infants randomized to PIOMI group were subjected to 5 minutes of PIOMI intervention three times daily for 7 consecutive days using all aseptic precautions with gloved fingers. The PIOMI is a 5-minute oral motor intervention that provides assisted movement to activate muscle contraction and provides movement against resistance to build strength [5]. Sham intervention consisted of unstructured stroking procedure done in and around the oral cavity of the infants.

Baseline oromotor evaluation was done in both the groups by a trained occupational therapist who had considerable experience of working in the neonatal unit and handling preterm babies. This occupational therapist was blinded to the group allocation and evaluation was done with a scale known as Neonatal Oro motor Assessment Scale (NOMAS) [6]. Maximum total score in NOMAS is 48 and higher score in NOMAS indicated better oro motor skills [7]. A repeat evaluation was again done by the same therapist after 7 days of intervention to eliminate inter-observer bias.

Primary outcome of the study was the improvement in the NOMAS score after 7 days of intervention. Secondary outcomes included transition time to reach full independent wati spoon feeds, duration of hospital stay and weight gain after intervention.

Study done by Fucile, *et al.* [8] had shown improvement in oro-motor skills with pre-feeding intervention. A sample size of 32 babies with 16 in each group was based on detecting a difference of 5 in NOMAS score between the PIOMI and the SHAM intervention group using a two sided alpha error of 0.05, beta error of 0.2 (power 80%) and a standard deviation of 5.

Statistical analysis: Baseline characteristics and outcome measures on continuous scales were analyzed by using two sample *t* test. Statistical analysis was performed by applying intention to treat principle and *P*<0.05 was considered statistically significant.

RESULTS

A total of 76 preterm infants less than 32 weeks were admitted in the unit during the 3 month study period out of which 42 were assessed for inclusion. Out of them, 30 were included in the study with 16 in PIOMI group and 14 in the sham intervention group (*Fig.* **1**). The baseline demographic characterstics of the enrolled infants were similar (*Table* **I**).

Improvement in mean (SD) NOMAS score over 7 days from baseline was also highly significant in the study group infants as compared to control group [9.25 (1.73) *vs* 4.79 (1.52), *P*<0.001*)*. Infants in the study group reached full *wati* spoon feeds significantly earlier than the infants in control group. There was a statistically significant increase in weight gain after enrolment in infants in study group than infants in control group. However, there was no significant difference in terms of hospital stay after enrolment, age at discharge, weight gain after enrolment and weight at discharge (*Table* **II**).
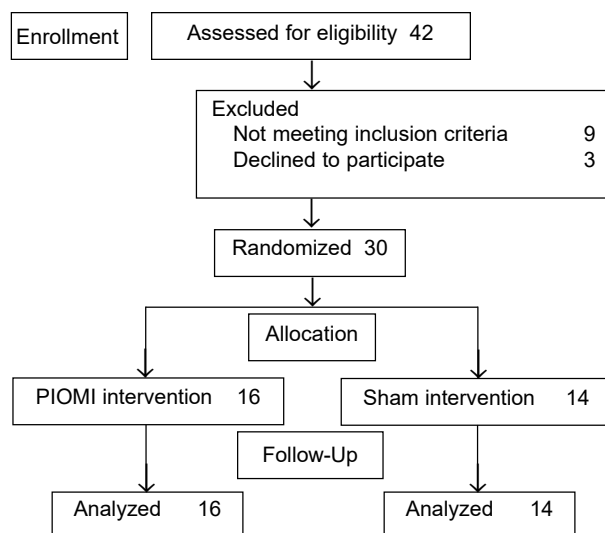

FIG. 1 *Flow of participants in the study.*

TABLE I BASELINE CHARACTERISTICS OF INFANTS IN TWO STUDY GROUPS

Variables	PIOMI intervention (n=16)	SHAM intervention (n=14)
#Gestation age (w)	30 (0.9)	30.5 (0.6)
#Birthweight (g)	1040.0 (120.6)	1063.6 (79.5)
Males	8 (50.0)	8 (57.1)
Antenatal Steroids received	13 (81.2)	9 (64.3)
Requirement of resuscitation	5 (35.7)	6 (42.8)
RDS	9 (64.2)	10 (71.4)
Culture positive sepsis	6 (37.5)	4 (28.5)
Mechanical ventilation	6 (37.5)	3 (21.4)
Non-invasive ventilation	11 (68.7)	12 (85.7)
#Trophic gavage feeds (d)	3.7 (1.4)	3.4 (1.6)
#Full oro-gastric feeds (d)	15.6 (4.2)	14.8 (5.1)
#Age at enrolment (d)	17.1 (4.5)	16.1 (4.7)
#Weight at enrolment (g)	1041.8 (108.6)	1067.9 (76.5)
NOMAS score at enrolment	27.1 (2.2)	28.6 (2.2)

Values in n(%) except #*Mean (SD); RDS: Respiratory distress syndrome; NOMAS: Neonatal oral motor assessment scale.*