Original Research Article

Comparative study on the effect of oral motor intervention protocols on oral motor skills of preterm infants from tertiary care hospital in metropolitan city: pilot study

Shailaja S. Jaywant¹, Jayashri S. Kale^{2*}

¹Department of Occupational Therapy, L. T. M. Medical College and G. H. Sion, Mumbai, Maharashtra, India

²Department of Occupational Therapy, Seth G. S. Medical College and K. E. M. H., Parel, Mumbai, Maharashtra, India

Received: 08 June 2020

Accepted: 19 June 2020

*Correspondence:

Dr. Jayashri S. Kale,

E-mail: shailaja_ot@yahoo.co.in

Copyright: © the author(s), publisher and licensee Medip Academy. This is an open-access article distributed under the terms of the Creative Commons Attribution Non-Commercial License, which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

ABSTRACT

Background: Premature infants often have feeding difficulties leading to morbidity or developmental co-morbidities. Premature infant oral motor intervention (PIOMI), has shown the positive effects on feeding progression of the premature infants. PIOMI with the massage technique, may help in improving oral motor activity, weight gain in preterm infants along with better neurobehavioral organization. The study was done to analyse effect of this combined protocol on achieving oral motor control and Neurobehavioral state regulation and evaluate its efficacy against PIOMI.

Methods: A total 72 clinically stable infants admitted in premature care unit, fulfilling inclusion criterion were enrolled. They were allocated in control and experimental group. Infants from control group received PIOMI and experimental group received PIOMI with massage therapy (M technique), for 10 minutes each day. Data was collected for oral motor abilities, behavioural assessment, weight and day of achieving full feeds.

Results: Gestational age at full feeds was 33.65 weeks and 32.89 weeks in control and experimental groups respectively with 'p' value 0.002. The number of days of full feed in experimental group was 3.7 days earlier ($p=0.04$). Infants from experimental group showed higher oral motor score and more weight gain with significant difference. The behavioral regulation in infants of both the groups improved after 8 day.

Conclusions: PIOMI with M technique was well tolerated by preterm infants. The modified protocol has resulted in achieving early oral feeds and reducing hospital stay. It has also shown the benefit of behavioural regulation along with better oral motor control.

Keywords: Behavioural regulations, Oral motor skills, Premature infant oral motor intervention

INTRODUCTION

Fifteen million infants are born Preterm every year globally i.e. 1 per 100 live births in India. One million preterm infants die due to lack of cost-effective care, warmth, breast feeding and breathing difficulties. Preterm infants frequently experience difficulties in oral-feeding due to underdeveloped oral motor skills and the lack of coordination of sucking, swallowing, and respiration.

Immature oral feeding ability has severe impact on the normal development of preterm infants and also increased the morbidity in this given population. Enteral milk feeding is critical for growth and development in this population. Once infant recovers from critical phase, its ability to feed orally is the main determinant length of hospitalization, physiologic stability and weight gain. Difficulty with oral feeding leads to longer hospital stays and higher costs.¹ The ability to feed orally can be

defined as the period when infants have the characteristics that enable them to take more than 80% of the prescribed total fluid intake orally in a twenty-four-hour period. Infant feeding is a complex process, requiring the precise coordination of Suck-Swallow-Breathe.²

Premature infant patterns differ from those of full-term infants.³ There is evidence that opportunity for nutritive sucking during early infancy, facilitates the oral feeding ability which further leads to perform the task effortlessly. The development of feeding pattern depends upon brainstem central pattern generators whose activity is increasingly influenced by chemosensory and oral tactile input.¹ There are no sources in the current document.

When lacking ability of self-feeding early intervention proves to be effective in initiation of early oral motor activity. Various oral motor stimulation programs that are designed often 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.³ In a study done by Cooper BM, the significant differences observed in sucking patterns related to the various behavioral states.⁴ The amount of time spent bursting was also affected by different behavioral state.

Dr. Brenda Lessen completed a pilot study on the effect of oral stimulation i.e., premature infant oral motor intervention (PIOMI) on feeding progression in preterm infants.⁵ The PIOMI demonstrates high interobserver reliability (97.57%), inter-user reliability (97.59%), and test-retest reliability (97.58%).⁵ Currently this protocol is used with Preterm Infants with feeding difficulties. The study done by Dr Karan et al has proved that infants receiving PIOMI reached full independent wati spoon feeds significantly earlier than the infants in control group.⁶ It is observed that gentle massage used in preterm infants has shown positive effect on hospitalized preterm infants. Study on use of gentle massage ‘M technique’ was conducted on very preterm infants, to estimate its effect on neurobehavioral organization i.e., physiologic, behavioral and state response in very preterm infants i.e. infants less than 30 weeks of PMA (post menstrual age).^{7,8} If oral motor stimulation given with massage therapy (M technique), it may help in improving oral motor activity in preterm infants along with better neuro-behavioral organization.

Thus, it can be cost effective and reduce burden on the Health care system. The protocol was designed to reduce behavioral stress while feeding, enhance neuronal mapping and neuro-development. This may help the Infant to develop oral motor skills and in reducing neurological morbidity in future.

This pilot study was done to analyse effect of the new oral motor intervention protocol on achieving oral motor

control and neurobehavioral state and evaluate its efficacy against PIOMI.

METHODS

The study design 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, or receiving oxygen per high-flow nasal cannula, due to very low gestational age, few infants needed oxygen supply for initial 3-4 days, 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. If Infants developed NEC during intervention, they are 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. As it was the first study to assess effect of new interventions on preterm infants born between 28 weeks and 32 weeks of gestation, it was considered as a pilot study, so the power of study was not taken into consideration. The sample size decided was 36 in each group, as per the workload 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 (such as improved feeding ability of infants, early discharge etc.) to their infants on participating in the study. They were assured about precautions taken while handling the infant.

Control group received protocol A, experimental Group received protocol B,

Initially thirty-six infants were included in each Group for pilot study. There were drop outs of 2 infants from experimental 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 (protocol A) PIOMI for 10 minutes, once a day. Infants from

experimental group (protocol B) received M technique consisted of series of massage on trunk and extremities for 5 minutes and PIOMI for 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 36 hours, 24 hours was ideal duration.⁵ 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. Some-times intervention needed to postpone next feeding period, if therapist has reached late, negative neuro-behavioral cues were also recorded during the intervention.

For both the groups assessment was done at the day of enrollment and follow-up was done at 4th and 8th day of the therapy using all the outcome measures (dependent variables), viz i.e., neonatal oral motor assessment scale (NOMAS) score, days of full feeds, length of hospital stay and Anderson behavioral state scale (ABSS).⁸ 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.

Safety

There were two instances throughout this study protocol was terminated because of adverse behavioral cues from

the infant. These infants gave negative signs such as hyperirritability showing score more than 10 on ABSS during intervention. Infants recovered after 2-3 minutes on discontinuing intervention. Later they were diagnosed as NEC and discontinued from the study.

RESULTS

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 ANOVA. The nominal data were tested with chi square χ^2 values. The primary dependent variable i.e., The NOMAS score was compiled and compared using Kruskal Wallis test and chi-square χ^2 values. Scores on Anderson behavioral state scale was analysed on contingency tables or using cross tabs.

Thirty-six infants were enrolled in each group. Four

mothers took discharge against medical advice from control group. Two infants from experimental group and two infants from control group developed NEC on day 3 of enrolment, so their data was excluded from initial analysis. Later, three mothers took early discharge against medical advice.

Thus, seventy infants were included at the initiation in the study 36 from control group receiving protocol A, 34 from experimental group receiving protocol B. During last follow-up results of 30 from control group and 31 from experimental group infants were analysed.

Figure 1: Pre and post intervention behavioral status in total population on Anderson behavioral status scale (ABSS).

Table 1: Gestational age of infants, age at enrolment, full feeds and days of full feed, days of hospital stay.

Dependant variables	Groups	N	Mean	Std Deviation	Std Error	95% confidence Interval for mean		F	Sig
						Lower bound	Upper bound		
Gestational age (in weeks)	Control	36	30.47	1.05	0.18	30.11	30.82	2.809	0.065
	Experimental	34	29.68	1.60	0.27	29.12	30.24		
Enrolment age (in weeks since gestation)	Control	36	31.57	0.89	0.15	31.27	31.87	0.707	0.495
	Experimental	34	31.43	0.92	0.16	31.12	31.75		
Age of full feed (in weeks since gestation)	Control	31	33.65	1.47	0.26	33.11	34.1	6.686	0.002
	Experimental	31	32.89	0.85	0.15	32.58	33.21		
Days for full feed	Control	30	14.23	8.02	1.46	11.23	17.22	5.875	0.004
	Experimental	31	10.52	4.82	0.86	8.75	12.28		
Duration of hospital stay (days)	Control	30	21.60	10.83	1.98	17.56	25.64	5.041	0.008
	Experimental	31	16.35	6.34	1.14	14.03	18.68		

‘p’ significant if ≤ 0.05 .

Table 2: Median scores and mean rank of Jaw and tongue score of NOMAS in experimental and control group during each follow-up.

Dependant variable		Control group	Experimental group	Chi square value	Asymptomatic Sig
Baseline NOMAS jaw score	Median score	15	13	5.660	0.059
	Mean rank	54.47	42.13		
Day 4 NOMAS jaw score	Median score	16	14	13.232	0.001
	Mean rank	47.81	40.78		
Day 8 NOMAS jaw score	Median score	18	16	21.666	0.000
	Mean rank	39.75	32.66		
Baseline NOMAS tongue score	Median score	14	12	3.675	0.144
	Mean rank	53.74	35.68		
Day 4 NOMAS tongue score	Median score	16	14	16.789	0.000
	Mean rank	48.83	40.10		
Day 8 NOMAS tongue score	Median score	18	18	19.055	0.000
	Mean rank	39.70	35.68		

‘p’ significant if ≤ 0.05

Table 3: The weight gain during each follow-up in both the groups.

Dependant variables	Groups		Mean difference In weight gain (I-J)	Std. error	95% confidence interval for mean		t value	Sig
	Group I	Group J			Lower bound	Upper bound		
Enrolment weight	Experimental	Control	142.27	69.23	184.15	-162.36	4.83	0.010
Weight gain on 4 th day	Experimental	Control	19.97	26.15	-31.29	71.23	0.755	0.100
Weight gain on 8 th day	Experimental	Control	27.55	68.51	-106.7	161.83	1.006	0.05

‘p’ significant if ≤ 0.05

Gestational age of infants at time of birth were 30.47 weeks and 29.68 weeks in control and experimental groups respectively, with ‘p’ value > 0.05 means both the groups were matched. There were 16 female infants and 20 male infants in control group, whereas 14 female

infants and 20 male infants in experimental group. There were 6 and 3 dropouts drop outs from control and experimental group respectively. Gestational age of achieving full feeds was 33.65 weeks and 32.89 weeks in control and experimental groups respectively with ‘P’

value 0.002. Also, the mean number of days for the control group to transition from gavage to total oral feedings was 14.23 days, compared with the experimental group i.e., 10.52 with $p=0.004$ (Table 1).

Then another covariate was analysed. Later NOMAS score was used to analyse oral motor skills, as seen in Table 2. Since the data is ordinal data, the data was analysed using Kruskal Wallis Test. The scores were analysed separately for the Jaw and the Tongue. The chi square value was calculated. The significant difference in median scores was observed during both the follow ups i.e. on the 4th day and on the 8th day. Infants from experimental group showed much higher median rank than control group subjects on jaw and tongue scores during follow ups (Table 2).

The hospital discharge also depends on the weight gain, so another covariate i.e., weight gain during intervention was analysed.

Initial difference was significant as weight of subjects in the lower and upper limits in control group had more difference than in experimental group. At 4 days follow up, the chi square value was not significant, as the difference in mean weight of subjects in both the groups was very minimal. Later the experimental group had achieved more weight gain with significant difference in lower bound and upper bound differences in the group with $p=0.05$ (Table 3).

Further the behavioral regulation of these infants were analysed using Anderson behavioral status scale on enrolment day, 4th day and 8th day of intervention. The behaviour was analysed 5 minutes pre-intervention and 5 minutes post intervention on follow-up days.

ABSS was divided in three categories as score 1 to 5=drowsy, score 6 to 8=stable, score 9 to 12=irritable. As observed in Figure 1, 88.2% of the infants in the experimental group were stable as compared to infants 75% from control group on the first day post-intervention. Similar trend was observed, in the difference between pre and post protocol on day 4 and day 8. There was no drowsy infant in experimental group on day 8th intervention after the protocol and only one infant showed irritability. The behavioral regulation in infants of both the groups improved after 8 days in pre and post intervention scores during each follow up (Figure 1). On 8th day 96.8% infants showed stable status as compared to control group subjects, 93% of subjects were stable post intervention in the control group (Figure 1).

DISCUSSION

The pilot study was designed to determine the effect of the new intervention protocol B, on preterm infants to enhance oral motor performance, achieving full feeds, length of hospital stay and behavioral regulation in

preterm infants. Pre-feeding stimulation in preterm infants reduces transition from gavage feeding to oral feeding and reduces duration of hospital stay.⁵

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 3.7 days faster than infants from control group. Infant massage received by infants in Group B has enhanced the neuro-behavioural regulation, may have hastened the coding of central pattern and thus the better feeding abilities earlier than the infants receiving PIOMI. As observed by Lau and Fucile, non-nutritive oral motor therapy (NNOMT) or infant massage therapy (iMT) provided singly and in combination shortens the number of days from start to independent oral feeding in very low birth weight infants.⁹

In another study on the review on the effects of tactile and kinesthetic stimulation on trunk and extremities on neonatal development in the premature infant, infants receiving massage therapy observed to be receiving greater amount of formula intake ($p<0.025$) and thus requiring less number of feedings, with early weight gain.¹⁰ When Bertoncelli N et al and others review the effect of sensorimotor stimulation with oral stimulation, the review found that oral and non-oral sensorimotor interventions, provided in combination demonstrated more advanced nutritive sucking, suck-swallow and swallow-respiration coordination than those who received an oral or sensorimotor intervention singly.¹¹ Similarly the infants in experimental group in the present study received the fixed oral motor intervention protocol i.e., PIOMI with structured M technique protocol, have shown early achievement of full feeds as compared to control group which received only PIOMI.

In the systemic review on “preterm infant massage therapy research: a review” it was observed that the massaged infants spent more time being active than the control infants and, nonetheless, they gained more weight. Also, there is increase in vagal activity, gastric motility, insulin and IGF-1 levels following moderate pressure massage and could be potential underlying mechanisms. Authors stated that above may be the reason for improving health and weight gain in preterm infants leading to early discharge.¹² Similarly in present study infants in the experimental group were discharged with an average of 5.2 days sooner than controls ($p=0.008$). The massage therapy with PIOMI, led to faster maturation of oral skills, with the enhanced gastric mobility and hence better weight gain, leading to early discharge.

As observed in the present study in table two, infants in experimental group showed oral motor control as per NOMAS, with higher median rank and $p=0.000$, for tongue and jaw scores, showing the improved oral motor

skills, leading to earlier full feeds. A study by Cilia Hardings, used NOMAS as outcome measures after non-nutritive stimulation on 14 preterm infants, between gestational age of 27 weeks to 35 weeks, has stated that the change in NOMAS scores after non-nutritive stimulations was higher median score of 9 as compared to control group scores 7 (Change of 7.1 and 4.6 respectively, with $p=0.034$). Their study suggested that relatively short periods of oral stimulation during non-nutritive sucking can benefit preterm infants by accelerating their progression to full oral feeding. The infants given non-nutritive sucking spent fewer days in hospital, took fewer days to reach full oral feeding and made more rapid progress on the NOMAS assessment, being more sensitive assessment.¹³ The infants in present study, from protocol B group showed significantly higher median rank on NOMAS and early achievement of full feeds as compared to control group.

When analysed for another covariant both experimental and control groups showed significant weight gain, viz control group and experimental group subjects gained average weight of 85 grams and 146 grams respectively in 8 days. Arora K et al stated that pre-feeding oral stimulation in preterm neonates (PIOMI) can result in significant weight gain.⁶ In present study infants receiving massage i.e., protocol B with PIOMI had greater weight gain and shorter hospital stay. In a study on 'weight gain in preterm infants following parent-administered Vimala massage: a randomized controlled trial', the infants from experimental group has shown neuro-behavioural regulation ability synchronized with gastric mobility as a result of massage therapy.¹⁴ Benefit of massage includes stimulation of circulatory and gastrointestinal systems, with neuro maturation.¹⁵ In the systemic review on massage therapy authors stated that the significant weight gain occurs after massage therapy with shortening of in-hospital stays of up to 6 days. The authors have stated that massage might increase basal metabolism and nutrient absorption through endocrine effects such as increase in insulin and adrenaline and decrease in cortisol.^{10,15} In this study, combined effect of improved oral motor control and better neuro-behavioural organization after intervention in experimental group, has enhanced oral motor abilities, with the improved gastric mobility leading to weight gain in infants.

The behavioral regulation in infants of both the groups improved after 8 days in pre and post intervention scores during each follow-up. In earlier study, the effect of Tactile-kinesthetic stimulation was observed on neurobehavioral parameters the test group showed better scores on the 'orientation', 'range of state', 'regulation of state' and 'autonomic stability' clusters. The improvement in latter two was seen as early as 5-7 days after commencement of stimulation.¹⁶ The infants in experimental group of this study maintained the behavioral status or improved their status five minutes post-intervention during assessment on follow-up days.

In a review by Gonzalez AP et al, while analyzing the effect of light pressure massage versus moderate pressure massage on state regulation of preterm infants, the authors have observed that moderate pressure massage appeared to be more relaxed and less aroused than the light pressure massage.¹⁴ Similarly, authors used moderate pressure massage administering protocol B, which may have resulted in better behavioral /state regulation.

Training parents to do the intervention under supervision of the therapist had enhanced parent/infant interaction. It is safe and simple to do. Many mothers reported feeling of satisfaction and more responsible towards infants. This has also resulted in better parent infant bonding.

The positive results are obtained with small sample size and it was a pilot study. Further larger sample size of infants with monitoring other vital factors such as the pulse and oxygen regulation using different oral motor stimulation techniques in preterm infants can be recommended. The long-term effects of stimulations were not examined in the present study. The mothers and care givers skills for feeding the infants orally was not considered.

The combined effect of pre-feeding stimulation with massage in experimental group has led to improved oral motor skills, improved feeding, leading to early weight gain and improved behavioral state regulation. This study has also given an additional perspective to consider the effect of behavioral status on feeding ability and weight gain in premature infants. The newly developed protocol B, PIOMI with M technique was well tolerated by infants between 28-32 of gestational age. It would be interesting to observe the continuation of early positive effect on infant feeding and compare the same after discharge.

Future studies might be considered for other benefits such as, an in-depth observation of neurodevelopmental status in infants in as a long-term effect. It should be studied further with larger population size and can be considered for multicenter trial.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Harding CM, Law J, Pring T. The use of non-nutritive sucking to promote functional sucking skills in premature infants: an exploratory trial. *Infant.* 2006;2(6):238-40.
2. Greene Z, Walshe M, O'Donnell CP. Effects of oral stimulation for oral feeding in preterm infants. *Cochrane Database Syst Rev.* 2012;3:CD009720.

3. Gaebler CP, Hanzlik, J. R. The effects of a prefeeding stimulation program on preterm infants. *Am J Occupat Ther*. 1996;50:184-93.
4. Medoff-Cooper B, Mcgrath JM, Shults J. Feeding patterns of full-term and preterm infants at forty weeks postconceptional age. *J Develop Behav Pediatr*. 2002;23(4):231-6.
5. Lessen BS. Effect of the premature infant oral motor intervention on feeding progression and length of stay in preterm infants. *Adv Neonat Care*. 2011;11(2):129-39.
6. Arora K, Goel S, Manerkar S, Konde N, Panchal H, Hegde D, Mondkar J. Prefeeding oromotor stimulation program for improving oromotor function in preterm infants - a randomized controlled trial. *Indian Pediatr*. 2018;55:675-8.
7. Smith JR, Raney M, Conner S, Coffelt P, McGrath J, Brotto M, Inder T. Application of the M Technique in hospitalized very preterm infants: a feasibility study. *Adv Neonat Care*. 2012;12(5S):S10-7.
8. Smith JR. Impact of a novel relaxation method of touch on neonatal neurobehavioral development among very preterm infants (Doctoral dissertation). 2013. Available at: <https://mospace.umsystem.edu/xmlui/handle/10355/35319>. Accessed on 12th March 2020.
9. Lau C, Fucile S, Gisel EG. Impact of nonnutritive oral motor stimulation and infant massage therapy on oral feeding skills of preterm infants. *J Neonatal-Perinat Med*. 2012;5(4):311-7.
10. Pepino VC. Application of tactile/kinesthetic stimulation in preterm infants: a systematic review. *J Pediatrics Res*. 2015;91(3):213-33.
11. Bertoni N, Cuomo G, Cattani S, Mazzi C, Pugliese M, Coccolini E, et al. Oral feeding competences of healthy preterm infants: a review. *Int J Pediatr*. 2012;2012.
12. Field T, Diego M, Hernandez-Reif M. Preterm infant massage therapy research: a review. *Infant Behavior Develop*. 2010;33(2):115-24.
13. Harding CM, Law J, Pring T. The use of non-nutritive sucking to promote functional sucking skills in premature infants: an exploratory trial. *Infant*. 2006;2(6):238-40.
14. Gonzalez AP, Vasquez-Mendoza G, García-Vela A, Guzmán-Ramírez A, Salazar-Torres M, Romero-Gutierrez G. Weight gain in preterm infants following parent-administered Vimala massage: a randomized controlled trial. *Am J Perinatol*. 2009;26(04):247-52.
15. Kulkarni A, Kaushik JS, Gupta P, Sharma H, Agrawal RK. Massage and touch therapy in neonates: the current evidence. *Indian Pediatr*. 2010;47(9):771-6.
16. Mathai S, Fernandez A, Mondkar J, Kanbur W. Effects of tactile-kinesthetic stimulation in preterms-a controlled trial. *Indian Pediatr*. 2001;38(10):1091-8.

Cite this article as: Jaywant SS, Kale JS. Comparative study on the effect of oral motor intervention protocols on oral motor skills of preterm infants from tertiary care hospital in metropolitan city: pilot study. *Int J Contemp Pediatr* 2020;7:1506-12.