ORIGINAL ARTICLE

The clinical effect of pacifier use on orogastric tube-fed preterm infants: A randomized controlled trial

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Abstract

Objective: To evaluate the clinical effect of pacifier use on orogastric tube-fed preterm infants.

Methods: The non-blinded randomised controlled study was conducted between October 2014 and November 2015 at the neonatal intensive care unit of a large public-sector hospital in Ankara, Turkey, and comprised preterm infants aged 31-36 gestational weeks with a birth weight of 1000g or above who had no congenital or neurological disease and were fed by orogastric tube. Through computer-generated simple randomisation, the subjects were divided into pacifier (intervention) and non-pacifier (control) groups. SPSS 17 was used to analyse data and compare the groups.

Results: There were 28 subjects; 14(50%) in each of the two groups. There was no difference between the groups in terms of gender, gestational age, birth weight, length, and head circumference ($p>0.05$). There was no difference in the weekly head, length, or girth measurements in the groups ($p>0.05$). In terms of daily weight gain, the intervention group gained 7gm more than the control group ($p<0.05$). The suction action of the pacifier group started earlier than the control group ($p<0.001$).

Conclusion: Preterm infants using pacifiers started total oral feeding earlier, gained more weight, and were discharged earlier than the control group.

Keywords: Preterm infant, Pacifier, Orogastric feeding, Nursing. (JPMA 69: 771; 2019)

Introduction

Coordination of sucking, swallowing and respiration is necessary for preterm infants to ensure effective and safe feeding,[1-3] and this coordination is completed in the 34th week of pregnancy.[4-6] Therefore, nutrition in preterm infants is an important challenge. Enteral feeding is the most secure way to maintain intestinal functions. As these babies breathe nasally, the orogastric tube (OGT) is the preferred feeding method.[7] Literature has reported that tube-fed preterm infants' transition to oral feeding is difficult because their sucking reflex is not supported, while for provision of nutritional needs, gain weight, and discharge from neonatal intensive care unit (NICU), sucking is one of the most important skills.[8] Therefore, it is important for infants to have various stimuli that will support sucking experiences in terms of infants' development of oral feeding abilities.[8,9] Among studies about interventions supporting the development of sucking skills for preterm infants, non-nutritive sucking has been reported to improve the skill, to ease transition to oral feeding, to shorten discharge time and to reduce medical cost.[3,4,8,10-14] There are many methods of non-nutritional nutrition (empty breast, pacifier, finger etc.) in the clinic.[15-17] Pacifier use improves non-nutritive sucking by oral stimulation.[7] The use of a pacifier induces serous and mucus secretions by stimulating the oral salivary glands of preterm infants and keeps the immature gastrointestinal tract (GIT) of preterm infants at a functional level, accelerates food absorption and increases weight gain and shortens oral feeding. It has been suggested that pacifiers should be used to accelerate the passage to full breastfeeding and to improve sucking skills in preterm infants fed both by oral feeding and complementary feeding in NICUs.[18] Pacifiers play an important role in non-nutritive sucking and the most accessible and easiest method.[19] The current study was planned to test the effect of pacifier use on various clinical parameters in OGT-fed preterm infants.

Subjects and Method

The non-blinded randomised controlled study was conducted between October 2014 and November 2015 at the NICU of a large public-sector hospital in Ankara, Turkey, and comprised preterm infants. The health facility has approximately 4000 live births per year.

Approval was obtained from the ethics committee of Ankara University and the institutional review board. Research was conducted according to the principles of the Declaration of Helsinki, and CONSORT 2010 was used as a guide in reporting.[20]

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The study included preterm infants aged 31-36 weeks with a birth weight of >1000gr and an Appearance, Pulse, Grimace, Activity, and Respiration (APGAR) score of 3 or more at the first minute, and of 5 or more points at the 5th minute and feeding with OGT. Preterms having had a surgical operation, having neurological disease symptoms, such as convulsion, having suffered central nervous system (CNS) bleeding, endotracheal intubation, congenital malformations, neurological and intestinal diseases were excluded.

According to the power analysis performed based on infants' length of hospital stay, the sample was calculated with 5% margin of error, 0.92 effect size and 82% power.

Preterm infants' sucking behaviour is affected by gestational maturity,[1,2,4] and to ensure similar distribution in the groups, infants were evaluated using New Ballards Scoring System (NBSS)[21] and were divided into two groups according to NBSS scores. Infants not using a pacifier represented the control group, while those using a pacifier formed the intervention group. The groups were formed using computer-generated simple randomisation. Since the randomisation was done by the researchers, no blindness could be achieved.

Both groups were fed according to the standard OGT feeding protocol of the NICU. The pacifier method was chosen because of the hospital's location, the number of beds in the mother's room, and the inability to reach the mother every hour. The subjects were fed with parenteral nutrition to an average of 12 hours that were required to supply the need for liquid, energy, macro (lipid, protein and glucose) and micro nutrients required for survival and growth.[22] After the normalisation of clinical parameters of the subjects, such as number of breaths, heart rate etc., they were started to be fed minimum enteral nutrition with OGT feeding under the supervision of a neonatalogist and nurse 12 hours after birth, and paranteral feeding was gradually reduced, and when the total enteral feeding got started, parenteral feeding was stopped. While this standard protocol was used for all infants, the intervention group was given pacifiers during the three feeding times. Each feeding was performed in the incubators, and lasted about 10 min. Pacifier application continued until total oral feeding. Infant used their own individual pacifiers which were sterilized before each use. The control group was not given the pacifiers during the feeding protocol.

Infant data form IDF, and daily and weekly tracking charts were developed for data collection.IDF includes 11 questions regarding gestational age, birth date, gender, APGAR score, discharge date etc. It was used to define infants' profile.[5,9,10,23]

Daily Tracking Chart (DTC) was used to record measurements including weight, peak heart-respiratory rate, body temperature, blood pressure, oxygen saturation, residual gastric volume, duration of OGT feeding, amount of food intake, the number of defecations, sucking movement etc. Weekly Tracking Chart (WTC) was used to record measurements of length, head and chest circumference. The equipments used for measurements were Charder MP-4200 digital scale (Charder Medical, Taiwan), Nihon Kohden SWM-7500 monitor (Nihon Kohden Europe GmbH, Germany), Braun Termoscanthympanic (Braun GmbH, Kronberg, Germany), standard chronometer, tape measure and GunDrop preterm infant nasal continuous positive airway pressure (nCPAP) pacifier (Natus Medical Incorporated, USA). All scales were calibrated before use.

Infants were weighed before their first feeding and they were fed according to the standard feeding procedure. Every day, before, during, and after the three OGT feedings, infants' peak heart rate, blood pressure, respiration rate, oxygen saturation, and body temperature were measured. Before feeding, the subjects' gastric residual volume (cc) was measured with an injector. The feeding duration was monitored using a chronometer. Non-nutritive sucking has inherently repetitive and rhythmic movements.[15] During the feeding, the baby's suction movements were observed. Sucking behaviour is considered successful with 3 consecutive and rhythmic sucking movements in which peristaltic tongue movements are synchronised with jaw movements.[10,24,25] Each diaper with defecation was weighed to assess the function of the gastrointestinal system.

Data was recorded on DTC. Once a week, infants' length, head and chest circumferences were measured using the same tape measure and data was recorded on WTC. The procedure continued until the infants made the transition to total oral feeding and their oral feeding transition, hospitalization duration (days) and discharge weight data was recorded.

SPSS 17 was used for data analysis. Descriptive data was expressed as frequencies, percentages, mean and standard deviation. The groups were compared using chi-square test and independent t-test.

Independent T-Test was used to assess the differences between the groups in terms of time to transition to oral feeding and discharge as well as daily/weekly measurements and vital signs at the relevant times.

Pearson's correlation and significance test of difference between the groups were used in the analysis of interobserver agreement to assess randomisation. P<0.05 was considered statistically significant.

Results

There were 28 subjects; 14(50%) in each of the two groups. Mean monitoring time of the subjects was 12±4,6 days; intervention group 8.92(±2,84) days, control group 16.21±6,39 days. There was no difference in terns of baseline characteristics of the two groups (p>0.05) (Table-1).

Table-1: Characteristics of control and pacifier groups.

Characteristics	Groups		Significance
	Control (n=14) Mean±SD	Pacifier (n=14) Mean±SD	
Ultrasound Gestational Age (USG)	32,71±0,26	32,71±0,16	p>0,05
Gestational Age	32,57±0,27	32,57±0,17	p>0,05
1 Minute Apgar	5,71±0,42	5,57±0,37	p>0,05
5 Minute Apgar	7,57±0,29	7,50±0,27	p>0,05
Birth Weight (gr)	1796,42±80,01	1877,14±79,08	p>0,05
Length At Birth (cm)	43,64±0,57	42,92±0,39	p>0,05
Head Circumferences (cm)	29,64±0,77	29,92±0,42	p>0,05
Chest Circumferences (cm)	27,96±0,37	27,67±0,56	p>0,05

Table-2: Comparisons of daily/weekly measurements of study groups.

	Groups		Significance
	Control (n=14) Mean±SD	Pacifier (n=14) Mean±SD	
Daily weight gain(gr)	6,54±1,28	13,68±2,41	t: 2,84 p=0,009
Daily number of stools	2,78±0,20	2,89±0,20	t: 0,39 p=0,689
Weekly head circumference increase (cm)	0,21±-0,26	-1,75±-1,56	t: -0,82 p=0,418
Weekly length growth (cm)	0,33±-0,03	-0,04±-0,04	t: -0,46 p=0,646
Weekly chest circumferences increase (cm)	0,17±-0,05	1,11±0,61	t: 0,53 p=0,596
Total oral feeding time (day)	16,21±1,71	5,42±0,41	t=-3,024 p=0,006
Length of stay in hospital (day)	16,21±1,71	8,92±0,75	t=-3,894 p=0,001
The weight at discharge (gr)	1886,42±73,41	1960,71±77,51	t=-3,017 p<0,001
Length of feeding (sec)	123,81±114,35	79,24±54,47	t= -1,317 p=0,199
Beginning of the suction (day)	6,07±3,04	1,71±0,99	t= -5,082 p<0,001

SD: Standard Deviation.

Table-3: Comparison of vital signs of study groups.

Measurement Time	Groups		Significance
	Control (n=14) Mean±SD	Pacifier (n=14) Mean±SD	
Body temperature			
Before feeding	36,66±0,13	36,67±0,18	p=0,887 t=0,144
During feeding	36,66±0,13	36,67±0,17	p=0,905 t=0,121
After feeding	36,66±0,13	36,67±0,17	p=0,905 t=0,121
Significance	r:1,000 p=0,336	r:1,000 p=0,336	
Heart Rate			
Before feeding	141,72±3,48	135,85±5,65	p=0,003 t=-3,305
During feeding	146,13±7,54	132,21±5,84	p<0,001 t=-5,456
After feeding	148,36±8,90	128,05±7,37	p<0,001 t=-6,573
Significance	r:0,475 t: -3,157 p=0,008	r:0,65 t: 5,148 p<0,001	
Respiratory rate			
Before feeding	51,77±1,75	51,71±1,75	p=0,936 t=-0,081
During feeding	53,56±2,61	49,41±6,65	p=0,039 t=-2,173
After feeding	54,37±3,89	47,28±6,04	p=0,001 t=-3,686
Significance	r:0,52 t:-2,907 p=0,012	r:0,40 t:2,99 p=0,01	
Blood pressure			
Before feeding- Systolic Value	67,37±5,90	64,38±6,74	p=0,222 t=-1,250
After feeding- Systolic Value	68,84±5,78	62,35±6,51	p=0,010 t=-2,787
Significance	r =0,915 t= 2,754 p=0,016	r =0,915 t= 2,754 p=0,016	
Before feeding- Diastolic Value	43,08±5,39	40,43±7,45	p=0,292 t=-1,075
After feeding-Diastolic Value	45,12±6,62	37,85±4,60	p=0,002 t=-3,372
Significance	r =0,874 t=-2,365 p=0,034	r =0,256 t=1,255 p=0,232	
Before feeding – Mean Value	51,31±4,90	48,47±5,51	p=0,162 t=-1,439
After feeding- Mean Value	52,96±5,43	46,60±5,06	p=0,004 t=-3,206
Significance	r =0,785 t=-1,802 p=0,095	r =0,714 t=1,745 p=0,105	
Oxygen saturation			
Before feeding	95,66±0,46	98,67±0,44	p=0,936 t=-0,081
During feeding	95,47±0,49	97,19±0,21	p=0,039 t=-2,173
After feeding	95,65±0,66	98,03±0,14	p=0,001 t=-3,686
Significance	r: 0,68 t:-3,52 p:0,006	r:0,52 t:0,025 p:0,98	

SD: Standard Deviation.

There were significant differences in discharge weight, total weight gain, time to total oral feeding, and length of hospitalisation ($p<0.05$), but there were no significant differences in daily number of stools and anthropometric measurement values between the groups ($p>0.05$) (Table-2).

The comparison of two groups' clinical parameters was done (Table-3).

The mean feeding duration was 79±54,47 sec in the pacifier group and 123±114,35 sec in the control group ($p>0.05$). The pacifier group on average showed sucking movement on the second day (2 days after birth) and the control group did it on the sixth day ($p<0.001$).

Discussion

Studies have focussed on non-nutritional absorptive (pacifier) interventions that support the suction reflex in preterm infants. These studies have determined that the daily weight gain of infants in the pacifier group during tube feeding was higher (7gm) than in the control group. Studies have determined that preterm infants who are given pacifiers during OGT feeding gained more weight.[5,8,18,25,26] Literature has stated that pacifier use keeps the GIT functional and regulates gastric motility by increasing the production of gastrin[11] and it has been concluded that infants gain weight due to these reasons.

It is shown that preterm infants given a pacifier during OGT feeding began to display sucking movements four days earlier than those in the control group. Tube-fed preterm infants' transition to oral feeding is difficult because their sucking reflex is not supported. For the provision of nutritional needs, to gain weight, and be discharged from NICU, sucking is one of the most important skills.[18] Studies indicated that pacifier use has positive effects on sucking success of preterm infants.[4,5,9,12,23]

Non-nutritive sucking has positive effects on feeding or swallowing as a oral motor intervention.[13] According to a meta-analysis, oral stimulation methods supported the transition to oral feeding in tube-fed preterms.[13] The present study determined that infants given a pacifier during feeding via OGT made the transition to total oral feeding approximately 11 days earlier ($p=0.006$), were discharged from the hospital 7 days earlier ($p=0.001$), and gained 74gm more weight ($p<0.001$). Studies have indicated that by using stimuli such as pacifiers in preterm infants shortens the time to transition to total oral feeding,[5,15,23,12,13,27-31] increases daily weight gain, and provides early discharge from NICU.[5,8,12,13,23,28,29,32,33] Therefore, it has been thought that pacifier use is an important implication in NICUs. After the preterm infant has gone through total oral feeding, the mother is directed to feed on her breast.

In the World Health Organisation (WHO)/United Nations Children's Fund (UNICEF) document, the Baby Friendly Hospital Initiative is offered worldwide as the gold standard care model to supporting breastfeeding.[34] In Turkey, according to the WHO's code of promotion of breastfeeding, the pacifier is not used in infants being breastfed. However, Baby Friendly Hospital Initiative Ten Steps to Successful Breastfeeding into Neonatal Intensive Care, Step 9 states that "pacifiers should be used for justified reasons". One of these justifiable reasons included infants being fed with tube.[35] Breastfeeding is culturally accepted in Turkey, but the use of pacifiers due to factors such as mother-infant separation or medical conditions may be considered therapeutic and may even provide medical benefits to reduce the risk of sudden infant death syndrome in infants.[36] It is suggested to use the pacifier to accelerate the passage to full breastfeeding and to improve sucking skills in preterm infants without oral feeding.[26] According to a meta-analysis, preterm infants fed through a tube in the stomach usually should be given a pacifier for sucking to improve feeding.[15] According to another meta-analysis, sucking on a pacifier during gavage feeding may encourage the development of sucking behaviour and improve digestion of the feeding.[12] The pacifier may only be used to support the suction reflex in preterms who cannot feed orally.

Another result of the present study is that the feeding duration of preterm infants using a pacifier was 44.5 sec shorter than those who did not use pacifier. Standley[9] stated that sucking was of shorter duration tube-fed preterm infants. This result may arise from the fact that gastric movements during sucking are faster.

Tachycardia is an unwanted condition that increases the workload of the heart in preterms. The present study found that the mean heart rate of infants given a pacifier was lower than those in the control group, a finding that is largely in agreement with literature.[23,37] In line with literature, we think that the decrease in the mean peak heart rate within normal ranges is associated with the pacifier as it calms babies down by making them awake and active, thus increasing adaption.[28]

The present study determined that the mean respiration rate in the pacifier group was lower, but the oxygen saturation during and after feeding in preterm infants using a pacifier was higher than those in the control group. Zhang et al.[31] reported no significant difference in oxygen desaturations between intervention and control

groups. Similar studies have reported that pacifier use in OGT-fed preterm infants is effective in keeping oxygen saturation values within normal ranges.[5,7,28] The number of swallowing motions is low in sucking without food, therefore sucking and respiration operate independently from one another.[38] This study concluded that oxygen saturation was within normal ranges because of this characteristic of sucking without food.

Though pacifier use supported babies' growth and development by providing better nutrition and weight gain, there were no significant effects of pacifier on anthropometric measurements. This result could be due to the shorter length of hospitalisation. There are no studies in literature about these variables. As such, further studies are needed.

The current study had no blinding and that was a limitation. Also, during the study period, due to technical reasons, the NICU did not admit neonatal babies at risk, and, therefore, the number of 33-week preterm infants was high in the study.

Conclusions

Pacifier use was found to have positive effects on vital signs, daily weight gain, transition to total oral feeding, and early discharge. NICU nurses can accelerate the preterm infants' transition to oral feeding by using pacifiers during tube-feeding to develop their sucking skills.

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