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Efficacy of Paladai versus Cup for Feeding of preterm Babies - A Randomized Controlled Trial

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Abstract

Introduction: The ideal way for infants to receive breast milk is through suckling at the breast. The different ways the neonates can receive supplemental milk are, paladai, cup, syringe, nasogastric tube. Studies have shown cup feeding is better. We routinely use paladai for feeding the preterm infants. Hence we studied the effect of paladai Vs cup on the efficacy of feeding.

Methodology: This was a Randomized controlled trial. Neonates were recruited based on inclusion criteria after the parental consent and randomly allocated to paladai or cup feed group. The intervention was given for total of 5 days. Duration of each feed, weight gain and vitals was monitored during the feed.

Statistical Considerations

Data was presented as Mean (SD) and Median for uniform and not uniform distribution respectively. Independent t test for normal distribututed groups or Mann- whitney U test for non-uniform groups. Categorical variables were analysed by Chi - square test. All statistical analysis was considered significant at 5% level.

Results: There were 17 neonates in each group(n=34).The median daily weight gain in paladai and cup feed was +8 gms, (IQR- 1.42 - 20)and+21.66gms(IQR-11.75-25) respectively with P = 0.05. The median time to reach required volume of feed was 24.38 mins (IQR-8.44-38.85) and 6.84 mins (IQR-1.43-16.14) in paladai and cup feed groups respectively with P=0.005.The oxygen saturation in the paladai and cup feeding was in (%) 94.29 ± 3.91 and 95.05± 2.77 respectively with P=<0.001

Conclusion: Cup feeding is better than paladai for feeding of Preterm Stable Neonates. Babies are more stable during cup feeding.

Keywords: Paladai feed, cup feed, preterm babies.

Introduction

In India preterm births are 3519100 each year[1].The nutrients are transferred from the mother to the fetus during the last gestational weeks leading to fetal weight gaining. Therefore, the premature neonates are deprived from such nutrition based on their gestational age[2].

Breast milk is complete nutrition for term and preterm infants and the ideal way for infants to receive breast milk is through suckling at the breast. Unfortunately, this may not always be possible for medical or physiological reasons such as being born sick or preterm and as a result requiring supplemental feeding. Currently, there are

various ways in which the neonates can receive feed is paladai, cup, syringe, nasogastric tube[3].

Oral feeding preterm babies are extremely a challenging factor. The common practice is to start with paladai feed as it was found a rapid improvement in feeding performance with experience – the median proficiency improved from 5.5 to 10.1 mL/min (group I) and 6.2–11.5 mL/min (group II)[2]. The investigator from her clinical experience found that paladai feeding is the arduous method. Mothers were scared to administer the feed first time and there is also a possibility of injury to the neonate's oral cavity because of its shape. Babies are taking long time to finish one feed and those who were fed with paladai, facing difficulty in direct breast sucking.

Further studies done on the effect of other methods of feeding the preterm neonates, it was found that Cup fed infants demonstrated significantly more mature breastfeeding behaviours when compared to bottle fed infants ($p < 0.01$) over six weeks, and had a significantly higher proportion of breast feedings one week after discharge ($p = 0.03$)[4].With these controversial findings, we aimed to compare the effect of paladai feed and cup feed on selected neonatal outcome(time to reach full volume of feed and the daily weight gain) among preterm babies

Methodology

This was a randomised controlled trial, conducted in NICU of tertiary care hospital, Bangalore. Thirty-four recruited preterm neonates were randomly allocated into paladai feeding group (A) and cup feeding group (B), using computer generated random numbers. Serially numbered opaque envelops with the randomization number were kept in the allocation concealment and was opened at the time of allocation.

To compare between the two groups, who are admitted to NICU

Primary objective: weight gain, time required for reaching required feeds in paladai Vs cup feeding

Secondary objective: The heart rate, respiratory rate and oxygen saturation

Inclusion criteria: Neonates with Birth weight - 1000 to 2000 gm, birth gestation 30 to 35 weeks and were hemodynamically stable and eligible for oral feeding.

Babies who were hemodynamically unstable were excluded from the study

Sample size was calculated based on the assumption 76.4 standard deviation (SD) in cup feed and 75.5 SD in paladai feeding with mean difference of 50.8 and 95% confidence level, the required minimum sample size was 17 in each group (total sample size = 34)[7]

The investigator fed the babies in both groups i.e. Group A (paladai), group B (cup) on the first day of the study, every second hourly. Subsequently mothers and staff nurse fed the babies after demonstration by the investigator for a total period of 5 days (study period) and till discharge. Night time feed was given by either mother or the staff nurses. A stop watch was used to monitor the duration of each feed and daily weight of the babies was recorded with a calibrated electronic weighing machine in the morning. Neonates in both groups were monitored by pulse oxymeter during each feeding session to check the variation in the physiological parameters like heart rate, respiratory rate and oxygen saturation.

Statistical analysis: Normally distributed data was presented as Mean (SD) and Median (Quartile 1, Quartile 3) for data not normally distributed. independent t test was used to compare between the groups and Mann-whitney U test for normally distributed and for not normal distributed variables respectively. Categorical

variables were analysed by Chi - square test. All statistical analysis was considered significant at 5% level. Data analysis was done using R (Version 3.4.3) software

Results

There were 34 neonates in the study group.

Baseline characteristic of neonates

Table 1: Description of baseline characteristic of Neonates N= 34

Sn.	Baseline variables of neonates	Paladai feed group		Cup feed Group		Test of significance	
		F	%	F	%	x^2/F	P value
1	Neonatal day						
	0-7 days	8	47.05%	11	64.70%	F	0.70
	8-15 days	4	23.52%	4	23.52%		
	>15 days	5	29.4%	2	11.76%		
2	Sex						
	Boy	13	76.4%	7	41.8%	3.03	0.08
	Girl	4	23.5%	10	58.8%		
3	Birth weight						
	1000g- 1500g	12	70.58%	11	64.70%		
	1501g-2000g	5	29.41%	6	35.29%	1.95	0.37

Table I shows there were no significant difference between the neonates in the two groups.

Section 2: comparison of neonatal outcomes between paladai feed group and cup feed group neonates

Table 2: Interquartile range, median and Mann Whitney 'U' test of effect of paladai feed and cup feed in preterm babies with change in daily weight and time to reach required volume of feed. n=34

Variables	Paladai feed		Cup feed		Mann Whitney 'U' test	P value
	Median	Interquartile range	Median	Interquartile range		
Change in daily weight(g)	+8.0	1.42 -20	+21.66	11.75-25	201.5	0.05
Time to reach required volume of feed (minutes)	24.38	8.44-38.85	6.84	1.43-16.14	225	0.005

There was a significant difference in daily weight gain and the time to reach the required volume of feed in the cup feed group as compared with paladai feed group at 0.05 level of significance.

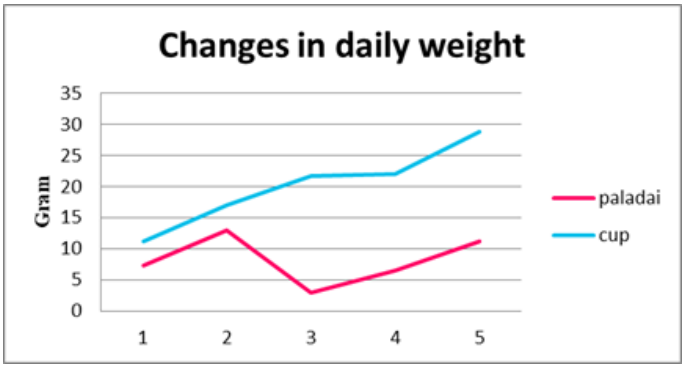

Figure 1: Line graph comparing the change in daily weight in paladai and cup feed group among preterm babies.(X- axis- study days, Y-axis- weight in grams)

Figure 1 depicts the change in the daily weight of preterm neonates in paladai feed group and cup feed group. Babies in paladai feed group shows regular pattern of the weight gain, whereas babies in cup feed group showed a steady weight gain and the weight gain is more compared to the babies in paladai feed group, which was statistically significant.

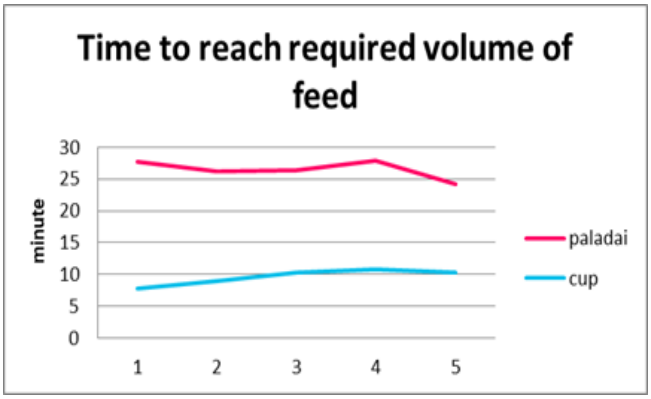

Figure 2: Line graph comparing the time to reach required volume of feed in paladai feed group and cup feed group among preterm babies.(X- axis- study days, Y-axis- time in minutes)

Babies in the cup feed group took less time to complete the required volume of feed as compared to the paladai feed group, which was statistically significant.

Table 3: comparison of effect of secondary neonatal outcome between paladai and cup feed group neonates on Spo_2, Heart rate, Respiratory rate n=34

Sn.	Paladai feed		Cup feed		Test of significance	P value
	Mean/median	SD/ IQR	Mean/median	SD/IQR		
Spo_2(%)	94.29*	3.91*	95.05	2.77	-3.92 (t)	<0.001
Heart rate	156.87*	15.68*	155.54	13.87	1.566(t)	0.117
Respiratory rate	56	52-58	56	54-58	118951.5(M-W)	0.001

Independent T Test(t), Mann Whintney 'U'Test(M-W),* Mean &SD

Table 3 shows there is a significant increase in the spo_2 in babies fed with cup, simultaneously the variability in the respiratory rate is reduced significantly in babies in cup feed group which is demonstrated by the reduced IQR. There is no significant change in the heart rate between two groups.

The paladai and cup used for the study

Paladai Cup

Discussion

Findings in the present study revealed that 47.05 % (8) of the babies in the paladai feeding group and 64.70% (11)

of the babies in the cup feed group were less than one week old.

Similarly, a study conducted in (USA2001) cup feeding for preterm infants showed that the mean post conception age of the infants in cup feeds were 34.5weeks ±1.5

In paladai feed group, majority of the neonates13(76.4%) were boys whereas in cup feed group, majority 10(58.8%) were girls. The homogeneity in the group 1 and group 2 was statistically tested and it was found that both groups were comparable. In agreement with the current study findings, a study done to assess physiologic stability of newborns during cup- and bottle-feeding showed that 26(51.0%) male and 25(41%) female was in the cup feed group and 12(48%) male and 13(52%) female in the bottle feeding group[15].

In this present study , majority of the neonates were born with birth weight of 1000g -1500g in both the groups ie 70.58% (12) and 64.7%(4) in cup and paladai feed groups respectively.

In this study, the median gain in weight scores after intervention of the preterm babies of cup feed group was +21.66 grams whereas for paladai feed group +8grams. The finding revealed that, there is statistically significant (P= 0.05) difference in the change in daily weight in the cup feed group and paladai feed group. Babies fed with cup have shown steady increase in the weight compared to those babies who were fed with paladai. The findings in this study is in congruent with the study by Christy M et al, where cup feeding was compared with other forms of supplemental enteral feeding for newborn infants unable to fully breastfeed found that the weight of the subject increased and helped the babies to suck the breast directly when fed with cup[5].

Another study by Yilmaz G et al , to assess the effect of cup feeding and bottle feeding on initiation of breastfeeding in late preterm infants showed that cup feeding significantly increased the likelihood of late preterm infants being exclusively direct breastfed at discharge and 3 and 6 months after discharge, and cup feeding did not increase the length of hospital stay as it also helps in increase of the baby weight[6].

Time to reach required volume of feed was assessed after each feed. The median of the time to reach required volume of feed in the cup feed group 6.84 minutes whereas 24.38 minutes in the paladai fed group which was statistically significant, (P=0.005) decrease in the time taken to the feed the babies with cup compared to the time taken to feed with paladai. The researcher was not able to find previous studies to compare with the finding of the present study in relation to time taken to feed the babies with the required volume of milk.

Limitations

The researcher fed the babies only for 5 feeds per day as against 12 feeds, the rest of the feeds were given by the nurses or the mothers, which might influence the outcome.

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