

EVALUATION OF THE EFFECT OF INTERVENTIONAL FEEDING PRACTICES ON GROWTH OF CLEFT LIP AND PALATE BABIESChandrashekar C¹, N. S. Mahantshetti², Leelavathy P. B³, Mohammed Abrar Sheriff⁴**HOW TO CITE THIS ARTICLE:**

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ABSTRACT: One year hospital based non-randomised trial to evaluate the effect of interventional feeding practices on the growth of cleft lip and palate patients was conducted at K.L.E.S's Hospital, Belgaum, Karnataka state, India. This trial was planned to study the various feeding modalities, the feeding problems, the incidence of morbidities, and the effect of different types of clefts on the growth parameters in control group. At the same time, evaluation of the effect of interventional feeding practices in terms of difference in the incidence of morbidities and the growth parameters between the interventional and control groups was studied. 22 and 33 cleft patients, who satisfied the criteria for the interventional and the control groups respectively, were enrolled for the trial. The feeding problems were quite prevalent in both the groups, with nasal regurgitation being the commonest, followed by vomiting and choking. Isolated cleft lip did not interfere with breast feeding as all the cases in both the groups practiced direct breast feeding. Cleft palate/lip interfered with the technique of direct breast feeding resulting in the practice of top feeds, commonly with cup and spoon modality even when the mother were eager to breast feed, indicating the less technical difficulties in the cup and spoon feeding modality. Isolated cleft lip did not have statistically significant over the growth parameters in contrast to the combined cleft palate and lip. There were no statistically significant differences in the growth parameters between males and females among different types of clefts in both interventional and control groups. The interventional feeding practices in combined cleft palate and lip cases resulted in statistically significant decrease in various morbidities and also better growth parameters. The use of obturators was not associated with improved growth parameters secondary to small sample size and inherent disadvantages of its application.

KEYWORDS: Isolated cleft lip, combined cleft palate and lip, interventional feeding practices, cup-spoon, obturator.

INTRODUCTION: Infants with cleft palate ± lip are likely to require at least some modification of feeding strategies that are used with infants who have no cleft palate ± lip. Feeding problems vary from minimal for an infant with an isolated cleft lip to major for infants with airway and neurological complications with a cleft palate ± lip. Parents want guidelines and information that will help them to help their infant feed efficiently.¹ Interestingly infants with clefts, despite their special needs and care giving requirements, stem not to have elevated risks for insecure attachments at the end of their 1st year.² Management of these special feeding problems depends on a detailed evaluation. Patience on the part of care givers and in some infants, creativity and innovation in the search for ways to maximize nutrition is required.³

Cleft lip ± palate are congenital defects that occur approximately one in every 750 births.⁴ Incidence varies among racial groups Caucasians are affected at a rate twice that of African Americans. Asians and Native Americans are affected at a rate of 1.5 times that of Caucasians. Isolated

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clefts of the palate occur at one in about 2, 500 births with less variation among racial groups. Incidence is higher in boys than in girls by nearly 2 to 1. Unilateral, left clefts are more common. When bilateral clefts occur, the left side is often more severely affected.

Weight gain in infants with palatal clefts has been a major concern to both clinician and parents. It has been assumed that such babies gain poorly in the early months of life because of low birth weight, feeding problems, psychosocial dynamics, the effect of associated malformations or some combination of this factors.⁵

Infants with more complex craniofacial anomalies, especially those involving airway compromises, typically demonstrate more severe feeding problems. For example, infants with Pierre-Robin sequence encounter feeding problems with the severity being proportional to the degree of airway obstruction.⁶

Primary surgical procedures consist of initial repairs of the lip or palate. Conventional wisdom is to repair the lip at 2 to 3 months of age. In palatal repair, there is no general consensus as to the optimal timing of repair relative to maxillofacial growth. It is usually done at around 18 months of age.⁷

OBJECTIVES OF THE STUDY:

The objectives of the present study are:

1. To identify the feeding problems in isolated cleft lip and cleft palate +/- lip patients.
2. To assess the impact of various types of clefts on the growth using Weight (kgs), Length (Cms) and Head Circumference (Cms) in the control group.
3. To suggest the proper feeding practices and later assess the growth in terms of weight (kgs), Length (Cms) and Head Circumference (Cms) upto 4-6 months of age by regular follow-ups, in the interventional group.

The suggested interventional feeding practices are:

- a) Advising specific breast feeding/top feeding techniques.
- b) Applying obturators (Feeding plates).

METHODOLOGY:

Source of Data: Babies attending cleft palate + lip O.P.D. at K.L.E.S.'s Hospital during the study period. Controls were also collected at the cleft palate + lip camps held by K.L.E.S.'s Hospital during the study period.

Type of Study: Non randomized control trial.

Study Period: AUG-2003 to JULY-2004.

Method of collection of Data:

Sample Size: 80% of the average of the last 2 years cases registered at cleft palate + lip O.P.D. at K.L.E.S.'s Hospital that is, about 20 cases.

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Inclusion Criteria for the interventional Group:

- Cases of age 0-2 months registered at cleft palate + lip O.P.D., K.L.E.S.'s Hospital during the study period.
- Cases may have isolated cleft lip, isolated cleft palate or both, unilateral or bilateral, complete or incomplete.
- Birth weight > 2 Kg.

Exclusion Criteria for the interventional Group:

- Age > 2 months at the time of registration to cleft palate + lip O.P.D. at K.L.E.S.'s Hospital.
- Associated congenital anomalies detected clinically which are known to interfere with growth such as congenital heart diseases, neural tube defects, gastrointestinal anomalies, chromosomal disorders etc.
- Birth weight < 2 kg.

Criteria for the controls of the Study:

- Age of 4-6 months at the time of registration to cleft palate + lip O.P.D., K.L.E.S.'s Hospital and in the camps held by the hospital during the study period.
- Patients may have isolated cleft lip, isolated cleft palate or both, unilateral or bilateral complete or incomplete.
- No associated congenital anomalies detected clinically which are known to interfere with growth such as, congenital heart diseases, neural tube defects, gastrointestinal tract anomalies, chromosomal disorders etc.
- Birth weight > 2 Kgs.
- Feeding interventions are not done in patients before the time of registration at the cleft palate + lip O.P.D., K.L.E.S.'s Hospital or at camps held by the hospital.

Interventions done (Only in the interventional Group):

- Teaching specific breast feeding technique in isolated cleft lip cases. To cover the gap (Cleft Lip) with thumb or breast tissue to generate adequate negative intra-oral pressure.
- Teaching specific top feeding techniques in cleft palate +/- lip patients.

Type of Milk: Depending on the socio economic status (Assessed by Modified Prasad's Classification) of the patient's attenders, formula or cow's milk was advised. In all the cases, breast milk was always encouraged if the mother was lactating at the time of registration at the cleft palate +/- lip O.P.D., K.L.E.S.'s Hospital.

Dilution of Milk: Formula - According to the manufacturer's recommendations Cows - undiluted milk was advised.

Quantity of the Milk: Quantity of the milk at the rate of 120 Kcal/Kg/Day was advised to all the cases irrespective of formula or cow's milk.

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Mode of Feeding: All the cases were given feeds by cup-spoon modality, without breach in the hygiene.

Position of the baby during Feeding. All the cleft palate +/- lip cases were fed in the upright position as recommended.

Use of Obturators: Depending on the discretion of the parents cases were fitted with obturators by an experienced orthodontist in the cleft palate +/- lip O.P.D., K.L.E.S.'s Hospital during the study period. Cases with obturators were followed every 10 to 15 days till 4 to 6 months of age.

Other Advices:

- To burp the cases adequately during and after feeds.
- Mothers were asked to feed the cases within 20 to 30 minutes, if possible.

METHODS: The cases in the interventional and the control groups were collected in the cleft palate + lip O.P.D., K.L.E.S.'s Hospital, which was held on every Monday and Thursday during the study period. Some of the controls were also collected in camps held by K.L.E.S.'s Hospital.

The cases were enrolled for the study as either the interventional group or the control group depending on the criteria satisfied by them. The relevant information provided by the parents about the cases in the interventional and the control groups were filled in the structured proforma/questionnaire.

The weight was checked using the Detecto Pan Type Weighing Machine. The length was taken by Infantometer. Head circumference was taken with an elastic non stretchable plastic tape at a maximum circumference around the glabella, supraorbital ridges and the occipital protuberance.

The advice regarding the feeding was given to the mothers in their own vernacular language. Counseling was done for all the cleft palate + lip cases regarding the obturators. The babies, whose parents agreed, were fitted with the obturators by an experienced orthodontist in the cleft palate + lip O.P.D., K.L.E.S.'s Hospital. They were followed once in 10 to 15 days by orthodontist.

All the cases in the interventional group were followed in the O.P.D. regularly till they were 4 to 6 months of age. Relevant information was entered in the structured proforma at every visit and weight, length and head circumference were measured. Feeding guidelines were again given.

The clinical study was carried out after taking the consent from the parents. The study was approved by the Ethical Clearance Committee, J. N. Medical College, Belgaum.

The Statistical Test of significance used is Wilcoxon Rank Sum Test (Adjusted for ties), Chi-square for goodness of fit Test and Fischer's Exact Test.

GENERAL DATA: 22 babies in the interventional group and 33 babies in the control group satisfied the criteria in this study. The study was conducted over a period of one year from August 2003 to July 2004.

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GENERAL DESCRIPTIVE INFORMATION OF THE INTERVENTIONAL AND THE CONTROL GROUPS:

Table No. 1: Distribution of isolated cleft lip cases.

Types		Interventional group		Control group	
		Number	Percentage	Number	Percentage
Unilateral	LEFT	02	50.00	07	77.77
	RIGHT	02	50.00	02	22.23
	TOTAL	04	100.00	09	100.00
Left : Right		1:1		3.49:1	

Table No. 1 shows the description of isolated cleft lip cases in the interventional and the control groups. In the interventional group, the distribution of left and right cleft lip cases were equal with ratio of 1:1 while in control group the number of left cleft lip cases were more than right cleft lip, the ratio being 3.49:1. None of our cases had bilateral cleft lip.

Table No. 2: Distribution of combined cleft palate and lip cases.

Types		Interventional group		Control group	
		Number	Percentage	Number	Percentage
Unilateral	Left	09	69.23	12	70.58
	Right	04	30.77	05	29.42
	Total	13	81.25	17	70.83
	Left:Right	2.25:1		2.39:1	
Bilateral		03	18.75	07	29.17
Total		16	100.00	24	100.00
Unilateral : Bilateral		4.33:1		2.42:1	

Table No. 2 shows the description of combined cleft palate and lip cases in the interventional and the control groups. In the interventional group majority (81.25%) had unilateral combined cleft palate and lip and 18.75% had bilateral combined cleft palate and lip with ratio of 4.33:1. In the control group majority (70.83%) had unilateral combined cleft palate and lip and 29.17% had bilateral combined cleft palate and lip, the ratio being 2.42:1. Among unilateral clefts in the interventional group, majority (69.23%) had left clefts and 30.77% had right clefts with ratio of 2.25:1 and in the control group, majority (70.58%) had left clefts and 29.42% had right clefts, the ratio being 2.39:1. The ratio of unilateral clefts was clearly matched but there was disparity in the unilateral: bilateral ratio, the number of cases being more in the interventional group as compared to the control group.

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Table No. 3: Distribution of isolated cleft palate cases.

Interventional Group	
Sex	Number
Male	02
Female	02
Total	04
Ratio	1:1

Table No.3 shows the general descriptive information of isolated cleft palate cases in the interventional group. Two cases had isolated cleft palate with male:female ratio of 1:1. There were no cases in the control group.

Table No. 4: Sex wise distribution of isolated cleft lip cases

Sex	Interventional group		Control group	
	Number	Percentage	Number	Percentage
Male	02	50.00	07	77.77
Female	02	50.00	02	22.23
RATIO	1:1		3.5:1	

Table No. 4 shows the male:female ratio of isolated cleft lip cases in the interventional and the control groups. The ratio varied from 1:1 in the interventional group to 3.5:1 in the control group, with more number of males in the control group.

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Table No. 5: Sex wise distribution of combined cleft palate and lip cases

Sex	Interventional group		Control group	
	Number	Percentage	Number	Percentage
Male	09	56.25	16	66.66
Female	07	43.75	08	33.34
RATIO	1.28:1		2:1	

Table No. 5 shows the male: female ratio of combined cleft palate and lip cases in the interventional and the control group. The ratio was almost identical in both the groups, being 1.28:1 in the interventional group and 2:1 in the control group.

DESCRIPTIVE INFORMATION OF FEEDING IN THE CONTROL GROUP

Table No. 6: Description of modes of feeding

Mode of Feeding	Isolated cleft lip		Combined cleft palate and lip	
	Number	%	Number	%
DBF	09	100.00	00	00.00
CS	00	00.00	09	37.50
BF	00	00.00	00	00.00
DBF + CS	00	00.00	05	20.83
BF + CS	00	00.00	09	37.50
DBF + CS + BF	00	00.00	01	04.17

(DBF-Direct Breast Feeding; CS-Cup-Spoon; BF-Bottle Feeding; DBF+CS- Direct Breast Feeding + Cup-Spoon; BF+CS- Bottle Feeding + Cup-Spoon; DBF+CS+BF- Direct Breast Feeding + Cup-Spoon + Bottle Feeding)

Table No. 6 shows different modalities of feeding, practiced by the control group. All the isolated cleft lip cases were exclusively breast fed. Among combined cleft palate and lip cases, none of them practiced exclusive breast feeding. Cup-spoon was used as the only modality in 37.50% cases and the remaining were fed by combination of different modalities. Among them 37.50% were fed by both bottle and cup-spoon, 20.83% were fed by both direct breast feeding and cup-spoon and the remaining 04.17% by all the three modalities (direct breast feeding, cup-spoon feeding and bottle feeding).

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INCIDENCE OF FEEDING PROBLEMS LIKE NASAL REGURGITATION, VOMITING AND CHOKING IN THE INTERVENTIONAL AND THE CONTROL GROUPS

Table No. 7: Combined cleft palate and lip and isolated cleft palate cases

Problems	Combined cleft palate and lip				Isolated Cleft palate	
	Interventional		Control		Interventional Group	
	Number	%	Number	%	Number	%
Nasal Regurg	14	88.88	22	91.66	02	100.00
Vomiting	12	77.77	15	62.51	02	100.00
Choking	07	50.00	14	58.33	02	100.00
Total Cases	16		24		02	

Table No. 7 shows the incidence of nasal regurgitation, vomiting and choking in combined cleft palate and lip and isolated cleft palate cases in the interventional and the control groups. The commonest problem in the combined cleft palate and lip, in the interventional and the control groups were nasal regurgitation. (88.88% vs. 91.66%) followed by vomiting (77.77% vs. 62.51%) and choking (50.00% vs. 58.33%) The two isolated cleft palate cases in the interventional group had all the above problems. None of the cases with isolated cleft lip had any of the above problems.

ASSOCIATION BETWEEN CLEFTS AND GROWTH PARAMETERS IN THE CONTROL GROUP

Table No. 8: Isolated cleft lip cases.

Groups	Weight		Length		Head Circum.	
	Number	%	Number	%	Number	%
Group V	01	11.11	00	00.00	01	11.11
Group IV	02	22.23	00	00.00	01	11.11
Group III	03	33.32	02	22.23	07	77.78
Group II	02	22.23	06	66.66	00	00.00
Group I	01	11.11	01	11.11	00	00.00
Total	09	100.00	09	100.00	09	100.00

Group I = > 75th Percentile, Group II = 51st - 75th percentile, Group III = 26th - 50th percentile, Group IV = 5th - 25th percentile and Group V = < 5th percentile (Percentiles are according to NCHS 2000 Charts)

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Table No. 8 shows the effect of isolated cleft lip on weight length and head circumference. Among the growth parameters, length was less affected when compared to weight and head circumference. Only 11.11% of cases showed failure to thrive with weight < 5th percentile and majority (55.55%) of the cases were in 25th to 75th percentile group. Length in majority (66.66%) of cases were in 51st to 75th percentile group. The head circumference of only 11.11% cases were in < 5th percentile group and majority (77.78%) of cases were in 25th -50th percentile group.

Table No. 9: Unilateral combined cleft palate and lip cases.

Groups	Weight		Length		Head Circum.	
	Number	%	Number	%	Number	%
Group V	13	76.47	08	47.05	11	64.70
Group IV	03	17.65	02	11.77	03	17.65
Group III	00	00.00	05	29.42	02	11.77
Group II	01	05.88	01	05.88	01	05.88
Group I	00	00.00	01	05.88	00	00.00
Total	17	100.00	17	100.00	17	100.00

Table No. 9 shows the effect of unilateral combined cleft palate and lip on weight, length and head circumference. Among the growth parameters, length was less affected when compared to weight and head circumference. Weight of majority (76.47%) of cases were < 5th percentile showing failure to thrive, which was statistically significant ($P = 0.0290$, Chi-square for goodness of fit Test). Head circumference of majority (64.70%) were in < 5th percentile group which was not statistically significant. ($P = 0.2162$, Chi-square for goodness of fit Test). The length of 47.05% of cases were < 5th percentile which was not statistically significant ($P = 0.8080$, Chi-square for goodness of fit Test).

Table No. 10: Bilateral combined cleft palate and lip cases.

Groups	Weight		Length		Head Circum.	
	Number	%	Number	%	Number	%
Group V	05	71.43	01	14.28	06	85.71
Group IV	02	28.57	01	14.29	01	14.29
Group III	00	00.00	05	71.43	00	00.00
Group II	00	00.00	00	00.00	00	00.00
Group I	00	00.00	00	00.00	00	00.00
Total	07	100.00	07	100.00	07	100.00

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Table No. 10 shows the effect of bilateral combined cleft palate and lip on weight, length and head circumference. Among the growth parameters, the length was less affected when compared to weight and head circumference. Weight of majority (71.43%) of cases were < 5th percentile showing failure to thrive, which was not statistically significant ($P = 0.2561$, Chi-square for goodness of fit Test). Head circumference of majority (85.71%) were in < 5th percentile group which was not statistically significant. ($P = 0.0587$, Chi-square for goodness of fit Test). The length of only 14.28% of cases were < 5th percentile which was not statistically significant ($P = 0.0587$, Chi-square for goodness of fit Test).

When unilateral and bilateral combined cleft palate and lip were taken together the association with between weight and head circumference were statistically significant with $P < 0.025$ and $P < 0.05$ respectively (Chi-square for goodness of fit Test) but not with length, $P > 0.1$ (Chi-square for goodness of fit Test).

MEAN EPISODES OF ARI, GE AND OTITIS MEDIA IN THE INTERVENTIONAL AND THE CONTROL GROUPS.

Table No. 11: Combined cleft palate and lip and isolated cleft palate cases.

Morbidity	Combined cleft palate and lip		Isolated Cleft palate
	Interventional	Control	Interventional
ARI	1.125	2.208	1.00
GE	0.312	1.208	0.50
Otitis media	0.125	0.208	0.00

ARI- Acute Respiratory Infection

GE-Gastro Enteritis

Table No. 11 shows the mean episodes of ARI, GE and Otitis media in combined cleft palate and lip and isolated cleft palate cases. In combined cleft palate and lip cases, the mean episodes of ARI, GE and Otitis media were more in the control group when compared with the interventional group (2.208 v/s. 1.125, 1.208 v/s. 0.312 and 0.208 v/s. 0.125) which were statistically significant only for ARI ($P = 0.0101$), GE ($P = 0.0242$) and not for Otitis Media ($P = 0.5595$) by Wilcoxon Ranksum Test. In isolated cleft palate cases of the interventional group, the mean episode of ARI, GE and Otitis media were 1.00, 0.50 and 0.00 respectively. There were no episodes of ARI, GE and Otitis media in isolated cleft lip cases in both the interventional and the control groups.

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GROWTH COMPARISON BETWEEN THE INTERVENTIONAL AND THE CONTROL GROUPS

1. Weight

Table No. 12: Weight comparison between isolated cleft lip cases

Groups	Interventional		Control	
	Number	Percentage	Number	Percentage
Group V	00	00.00	01	11.11
Group IV	00	00.00	02	22.22
Group III	00	00.00	03	33.34
Group II	04	100.00	02	22.22
Group I	00	00.00	01	11.11
Total	04	100.00	09	100.00

Table No. 12 shows the weight comparison of isolated cleft lip cases between the interventional and the control groups. 11.11% of cases in the control group showed failure to thrive with weight < 5th percentile as compared to none in the interventional group which was not statistically significant (P = 0.6923, Fischer's Exact Test).

Table No. 13: Weight comparison between combined cleft palate and lip cases.

Groups	Interventional		Control	
	Number	Percentage	Number	Percentage
Group V	05	31.25	18	75.00
Group IV	07	43.75	05	20.84
Group III	02	12.50	00	00.00
Group II	02	12.50	01	04.16
Group I	00	00.00	00	00.00
Total	16	100.00	24	100.00

Table No. 13 shows the weight comparison of combined cleft palate and lip cases between the interventional and the control groups. Majority (75.00%) of cases in the control group showed failure to thrive with weight < 5th percentile as compared to only 31.25% of cases in the interventional group which was statistically significant (P = 0.0204, Fischer's Exact Test).

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2. Length

Table No. 14: Length comparison between isolated cleft lip cases.

Groups	Interventional		Control	
	Number	Percentage	Number	Percentage
Group V	00	00.00	00	00.00
Group IV	00	00.00	00	00.00
Group III	00	00.00	02	22.23
Group II	04	100.00	06	66.67
Group I	00	00.00	01	11.11
Total	04	100.00	09	100.00

Table No. 14 shows the length comparison of isolated cleft lip cases between the interventional and the control groups. All the cases in the interventional group and majority (66.67%) of the control group were in 51st to 75th percentile group.

Table No. 15: Length comparison between combined cleft palate and lip cases.

Groups	Interventional		Control	
	Number	Percentage	Number	Percentage
Group V	01	06.25	09	37.50
Group IV	03	18.75	03	12.50
Group III	08	50.00	10	41.60
Group II	04	25.00	02	08.30
Group I	00	00.00	00	00.00
Total	16	100.00	24	100.00

Table No. 15 shows the length comparison of combined cleft palate and lip cases between the interventional and the control groups. 37.50% of cases in the control group were < 5th percentile as compared to only 06.25% of cases in the interventional group which was statistically significant (P = 0.0270, Fischer's Exact Test).

3. Head Circumference.

Table No. 16: Head Circumference comparison between isolated cleft lip cases.

Groups	Interventional		Control	
	Number	Percentage	Number	Percentage
Group V	00	00.00	01	11.11
Group IV	00	00.00	01	11.11
Group III	04	100.00	07	77.78
Group II	00	00.00	00	00.00
Group I	00	00.00	00	00.00
Total	04	100.00	09	100.00

Table No. 16 shows the head circumference comparison of the isolated cleft lip cases in the interventional and the control groups. 11.11% of cases in the control group were < 5th percentile as compared to none in the interventional group which was not statistically significant ($P = 0.6923$, Fischer's Exact Test).

Table No. 17: Head Circumference comparison between combined cleft palate and lip cases.

Groups	Interventional		Control	
	Number	Percentage	Number	Percentage
Group V	03	18.75	17	70.84
Group IV	05	31.25	04	16.66
Group III	06	37.50	02	08.34
Group II	02	12.50	01	04.16
Group I	00	00.00	00	00.00
Total	16	100.00	24	100.00

Table No. 17 shows the head circumference comparison of combined cleft palate and lip cases in the interventional and the control groups. Majority (70.84%) of cases in the control group were < 5th percentile as compared to only 18.75% of cases in the interventional group which was statistically significant ($P = 0.0031$, Fischer's Exact Test).

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GROWTH PARAMETERS OF ISOLATED CLEFT PALATE CASES IN THE INTERVENTIONAL GROUP

Table No. 18: Isolated cleft palate cases.

Groups	Weight		Length		Head Circum.	
	Number	%	Number	%	Number	%
Group V	02	100.00	00	00.00	01	50.00
Group IV	00	00.00	01	50.00	01	50.00
Group III	00	00.00	01	50.00	00	00.00
Group II	00	00.00	00	00.00	00	00.00
Group I	00	00.00	00	00.00	00	00.00
Total	02	100.00	02	100.00	02	100.00

Table No. 18 shows the weight, length and head circumference of isolated cleft palate cases in the interventional group. Length was less affected when compared to weight and head circumference. All the cases showed failure to thrive with weight < 5th percentile. Length of the cases were equally represented in both 5th – 25th percentile and 26th – 50th percentile group. Head circumference of 50% cases were <5th percentile, with other 50% in 5th – 25th percentile group.

ASSOCIATION BETWEEN OBTURATOR AND GROWTH PARAMETERS OF COMBINED CLEFT PALATE AND LIP CASES IN THE INTERVENTIONAL GROUP

Table No. 19: Association between obturator and weight

Groups	Obturator		Non-Obturator	
	Number	Percentage	Number	Percentage
Group V	03	75.00	02	16.66
Group IV	01	25.00	06	50.00
Group III	00	00.00	02	16.67
Group II	00	00.00	02	16.67
Group I	00	00.00	00	00.00
Total	04	100.00	12	100.00

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Table No. 19 shows the weight comparison of combined cleft palate and lip cases in the obturator and non-obturator group. Majority (75.00%) of the cases in the obturator group were associated with failure to thrive, with weight < 5th percentile as compared to only 16.66% of cases in the non-obturator group which was not statistically significant (P = 0.0631, Fischer's Exact Test).

Table No. 20: Association between obturator and length.

Groups	Obturator		Non-Obturator	
	Number	Percentage	Number	Percentage
Group V	00	00.00	01	08.33
Group IV	03	75.00	00	00.00
Group III	01	25.00	07	58.24
Group II	00	00.00	04	33.33
Group I	00	00.00	00	00.00
Total	04	100.00	12	100.00

Table No. 20 shows the length comparison of combined cleft palate and lip cases in the obturator and the non-obturator groups. 08.33% of cases in the non-obturator group were associated with length < 5th percentile as compared to none in the obturator group which was not statistically significant (P = 0.750, Fischer's Exact Test).

Table No. 21: Association between obturator and head circumference.

Groups	Obturator		Non-Obturator	
	Number	Percentage	Number	Percentage
Group V	01	25.00	02	16.67
Group IV	03	75.00	02	16.67
Group III	00	00.00	06	50.00
Group II	00	00.00	02	16.66
Group I	00	00.00	00	00.00
Total	04	100.00	12	100.00

Table No. 21 shows the head circumference comparison of the combined cleft palate and lip cases in the obturator and the non-obturator groups. 25.00% of cases in the obturator group were

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associated with head circumference < 5th percentile as compared to only 16.67% of cases in the non-obturator group which was not statistically significant (P = 0.8642, Fischer's Exact Test).

DISCUSSION: In the present study, at the time of enrollment almost all the mothers in the cleft palate + lip interventional group were in lactation failure with top feeding their cleft babies. We don't have a lactation consultant to re lactate them and at the same time, we don't advice bottle feeding as it is against our pediatric association guidelines and also for its unhygienic method carried by our poorly educated mothers. We were left with only cup-spoon option, which could be carried out easily with maintaining adequate hygiene by even poorly educated mothers, with little or no technical difficulties. Hence we advised cup-spoon method of feeding with easily accessible type of milk i.e. cow's milk with upright posture of the babies during feeding with adequate and frequent burping as described in methodology. We measured the effectiveness of cup-spoon on the growth parameters [weight (Kg), length (Cms) and head circumference (Cms)] and also on the incidence of morbidities (ARI, GE and Otitis media). All the isolated cleft lip cases in the interventional group were advised direct breast feeding, as it did not interfere with techniques of breast feeding.

In the present study, the mean age of enrollment of cases in the interventional group was 1.05 months. The interventions as described in the methodology were done in the interventional group. The mean number of follow-ups done was 3.09 till the mean age of 4.90 months.

At the same time we studied the various kinds of feeding practices prevailing in the control group, with the effect of clefts on their growth. The mean age of enrollment of cases in the control group was 4.70 months. The various kinds of feeding patterns were studied in them. All the isolated cleft lip cases were on direct breast feeds indicating that the defect did not interfere with techniques of direct breast feeding. Most of the cleft palate + lip cases were on top feeds indicating that the defect interfered with techniques of breast feeding as initially they were tried with direct breast feeding in vain. The quantity of milk fed to them ranged from ½ wati – 1 wati (1 Wati = 100 ml) with number of feeds per day in the range of 5 to 8. Dilution of the milk (milk: water) ranged from 1:10 – 4:1 with majority over diluting the milk. All the cases that were practicing breast feeding were fed in 'C' position.

In the top fed babies, only one was fed in upright position and the remaining in supine position. The effect of the cleft types and also the feeding patterns on the growth, in the control group were studied in terms of weight (Kgs), Length (Cms), Head Circumference (Cms) and number of episodes of ARI, GE and Otitis Media.

GENERAL DESCRIPTIVE INFORMATION OF THE INTERVENTIONAL AND THE CONTROL GROUPS:

In the present study, combined cleft palate and lip was the commonest defect followed by isolated cleft lip and isolated cleft palate in both the interventional and the control groups (72.72% v/s 72.73%, 18.18% v/s 27.27% and 09.10% v/s 00.00 respectively). Irrespective of the groups, unilateral defect was more common than bilateral defect in both isolated cleft lip and combined cleft palate and lip cases (4.33:1 v/s 2.42:1) and among unilateral defects, left sided were more common than right sided (2.25:1 v/s 2.39:1) (Table No. 1, 2 and 3, Photograph No. 1, 2 and 3). Similar observations were made by Jensen B. in 1998, by studying the epidemiology of cleft babies from 1976-1981 in Denmark and reported that, combined cleft palate and lip (39.10%) is the most common defect followed by isolated cleft lip (33.50%) and isolated cleft palate (27.40%). He also

observed a significant predominance of unilateral clefts and left sided clefts were twice as common as right sided.⁵⁴

DESCRIPTIVE INFORMATION OF FEEDING IN THE CONTROL GROUP:

Modes of feeding in the control Group: In the present study, all the isolated cleft lip cases were practicing direct breast feeds indicating that the defect did not interfere with techniques of breast feeding. All the combined cleft palate and lip cases were initially tried with direct breast feeding and since the defect interfered with the techniques of breast feeding, majority of them practiced cup-spoon or bottle and cup-spoon (37.50% each) followed by combined direct breast feeding and cup-spoon in 20.83% and all the three modalities (DBF, BF and CS) in 04.17% of cases with the resultant lactation failure.

So various kinds of feeding modalities were prevailing in the infants of combined defect, which may have negative influence over the growth and development. (Table No. 9) Oliver R. G. in 1994, studied the feeding practices in the cleft infants in South Wales, and reported that in the isolated cleft lip group 64.00% were bottle fed, 50.00% were breast fed and 04.00% were fed by combination. In cleft palate and lip group, 90.00% were bottle fed, 23.00% were tube fed, 03.00% were breast fed and another 03.00% were fed by combination (Where total exceeds 100%, a combination of feeding methods were employed and combination type indicates that different methods were employed, where details were not divulged by parents).¹

The prevalence of different feeding modalities is secondary to:

1. The different types of feeding problems encountered in the cleft infants.
2. Over the time, mothers develop their own way of feeding, which is best suited for their cleft infants.
3. Influence of community e.g. in our community breast feeding is always encouraged and if breast feeding is not possible cup-spoon modality is encouraged and the bottle feeding is discouraged due to its breach in hygiene.

INCIDENCE OF FEEDING PROBLEMS LIKE NASAL REGURGITATION, VOMITING AND CHOKING IN

THE INTERVENTIONAL AND THE CONTROL GROUPS: In the present study, there were no feeding problems in the isolated cleft lip cases and hence all were fed by direct breast feeds in accordance to a study done by Pandya A. N. in 2001.¹² In the combined cleft palate and lip cases the most common feeding problem was nasal regurgitation (88.88% v/s 91.66%) followed by vomiting (77.77% v/s 62.50%) and choking (50.00% v/s 58.33%) in both the groups. The two cases of isolated cleft palate in the interventional group had all the above problems (Table No. 7).

In a study done by Lee J. in 1996, it was reported that 55.00% of the combined cleft palate and lip infants and 83.90% of isolated cleft palate infants had the feeding problems. The most common type of feeding problem reported were nasal regurgitation followed by vomiting.¹⁴

The results were almost comparable, but the increased frequency of the feeding problems in our study could be secondary to the multiple modalities of feeding tried and employed with faulty techniques by the parents and also due to their low socio-economic status.

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ASSOCIATION BETWEEN CLEFTS AND GROWTH PARAMETERS IN THE CONTROL GROUP:

Isolated cleft Lip: In the present study, only 1 case (11.11%) of isolated cleft lip showed failure to thrive with weight < 5th percentile, while majority were above 26th percentile. Length of majority (77.77%) were above 50th percentile, head circumference of majority (77.78%) were between 26th to 50th percentile. Majority of the isolated cleft lip cases had a near normal growth in all the three growth parameters. Hence isolated cleft lip is not associated with poor growth parameters (Table No. 8, Photograph No. 4).

Similar observations were made by Kaufman F. L. in 1991 in review of managing the cleft patients and concluded that, isolated cleft lip cases do grow normally.⁽⁷⁾ In another study done by Pandya A. N. in 2001, it was reported that failure to thrive of 8-9% isolated cleft lip patients appeared to be similar to the normal range.¹²

Hence the results of present study were in accordance with the above two studies.

Combined cleft palate and Lip: In the present study, 76.47% unilateral cases and 71.43% bilateral cases showed failure to thrive with weight < 5th percentile, the length was < 5th percentile in 47.05% unilateral cases and 14.28% bilateral cases and the head circumference was < 5th percentile in 64.70% unilateral cases and 85.71% bilateral cases. (Table No. 9, 10, Photograph 5)

In a study done by Pandya A. N. in 2001 on failure to thrive in babies with cleft palate and lip, it was reported that 32.00% of unilateral and 38.00% of bilateral cases showed failure to thrive with weight < 5th percentile.¹²

In a study done by Lee J. in 1996 on height achievement in cleft palate and lip cases, it was shown that cleft palate and lip was not significantly associated with adverse height outcome.¹⁴ To the best of our knowledge, there are no studies showing association of cleft types with adverse head circumference.

Hence in present study combined cleft palate and lip cases were associated with poor growth in all the three parameters, (Weight, Length and Head Circumference) although, weight and head circumference were more affected than length, which were statistically significant. It may be secondary to:

1. Low socio-economic status.
2. The multiple feeding modalities followed with low quality and quantity of milk with faulty feeding techniques.
3. Increased incidence of feeding problems like nasal regurgitation and vomiting.
4. Increased prevalence of ARI, GE and Otitis Media.

In the present study, why length was less affected compared to weight and head circumference needs to be explained with through further studies on a larger sample size.

MEAN EPISODES OF ARI, GE AND OTITIS MEDIA IN THE INTERVENTIONAL AND THE CONTROL GROUPS: In the present study, the mean episodes of ARI, GE and Otitis media were 2.208, 1.208 and 0.208 respectively. (Table No. 11)

In a study done by Schollaart B. T. in 1989, it was reported that mean episodes of ARI and GE were 0.8 and 0.3 respectively. It was also reported that the airway infections between 0 and 3 months of age accounted for 14% variance in the weight.¹⁵

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Increased prevalence of ARI and GE in the control group of the present study may be secondary to:

1. Low socio economic status.
2. Faulty feeding techniques.
3. Increased prevalence of malnutrition in the control group.
4. Increased incidence of feeding problems like, nasal regurgitation and vomiting.

MEAN EPISODES OF ARI, GE AND OTITIS MEDIA IN INTERVENTIONAL V/S. CONTROL GROUPS:

In the present study, the mean episodes of ARI, GE and Otitis media (1.125, 0.312 and 0.125) in the interventional group were less when compared to control group (2.208, 1.208 and 0.208) which were statistically significant for ARI and GE indicating that the intervention done has decreased the number of episodes of ARI and GE in the interventional group (Table No. 11).

GROWTH COMPARISON BETWEEN THE INTERVENTIONAL AND THE CONTROL GROUPS:

Weight: In the present study, only 11.11% of isolated cleft lip cases in the control group showed failure to thrive with weight < 5th percentile as compared to none in the interventional group which was not statistically significant (Table No. 12).

This is in accordance to a study done by Pandya A. N. in 2001, where the incidence of failure to thrive in isolated cleft lip cases decreased from 09.00% in the control group to 08.00% in the interventional group although not statistically significant.¹²

In the present study combined cleft palate and lip group, majority (75.00%) in the control group showed failure to thrive with weight < 5th percentile as compared to only 31.25% of cases in the interventional group which was statistically significant (Table No. 13). Although the incidence of failure to thrive was more in the present study, similar observations were made by Pandya A. N. in 2001 and reported that, the incidence of failure to thrive of combined cleft palate and lip cases decreased from 34.15% in the control group to 12.50% in the interventional group, which was statistically significant.¹²

Length: In the present study, isolated cleft lip cases irrespective of the interventional and the control group, majority (100% v/s 66.67%) were > 50th percentile (Table No. 14).

In the present study, 37.50% of combined cleft palate and lip cases in the control group were <5th percentile as compared to only 06.25% of cases in the interventional group which was statistically significant (Table No. 15).

To the best of our knowledge, no other studies have reported about the length outcome in combined cleft palate and lip cases after of the interventional feeding practices.

Head Circumference: In the present study, only 11.11% of isolated cleft lip cases in the control group were <5th percentile compared to none in the interventional group which was not statistically significant. (Table No. 16)

In the present study, majority (70.84%) of combined cleft palate and lip cases in the control group were < 5th percentile compared to only 18.75% of cases in the interventional group which was statistically significant (Table No. 17).

To the best of our knowledge, no other studies have reported about head circumference outcome in combined cleft palate and lip cases after the interventional feeding practices.

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Our study definitely shows that the intervention done in the cases had positive correlation on the growth parameters as the observations were statistically significant.

GROWTH PARAMETERS OF ISOLATED CLEFT PALATE CASES IN THE INTERVENTIONAL GROUP:

In the present study, all the cases showed failure to thrive with weight <5th percentile (Table No. 18).

In a study done by Pandya A. N. in 2001, incidence of failure to thrive with weight < 5th percentile in isolated cleft palate cases of the interventional group was 26.00%.¹ The increased incidence of failure to thrive in the present study may be secondary to:

1. Less number of cases.
2. The effect of isolated cleft palate.
3. Increased prevalence of feeding problems.

In the present study, none of the cases showed length < 5th percentile, while head circumference of 50.00% of the cases were < 5th percentile (Table No. 18)

In a study done by Lee J. in 1996 on height achievement in isolated cleft palate cases, it was shown that isolated cleft palate was not significantly associated with adverse height outcome. To best of our knowledge, there are no studies showing association of isolated cleft palate with adverse head circumference.¹⁴

ASSOCIATION BETWEEN OBTURATOR AND GROWTH PARAMETERS OF COMBINED CLEFT PALATE AND LIP CASES IN THE INTERVENTIONAL GROUP:

In the present study, majority (75.00%) of cases in the obturator group showed failure to thrive with weight <5th percentile compared to only 16.66% of cases in the non-obturator group which was not statistically significant. Length of 08.33% of cases in the non-obturator group were < 5th percentile compared to none in the obturator group which was not statistically significant. Head circumference of 25.00% of cases in the obturator group were < 5th percentile compared to only 16.67% of cases in the non-obturator group which was also not statistically significant (Table No. 19, 20 and 21, Photograph No. 6).

Hence in the present study, obturator had negative effect on growth parameters of combined cleft palate and lip cases rather than neutral or positive effect although not statistically significant.

In a randomized study done by Prah C. in 1996, it was reported that there was no benefit of obturator on feeding frequency, food intake or velocity of food intake and finally on growth during the first 24 weeks of life, in infants with cleft palate and lip.⁴⁰ In a Cochrane review by Glenn A. M. in 2004, it was shown that there was no statistically significant difference in the growth of cleft palate and lip infants fitted with maxillary plate (obturator) compared to no plate.⁵³ The reasons for negative effect in the present study may be secondary to:

1. The obturator requires lot of motivation for its application and maintenance, because of its clumsy and prolonged hours of application and very frequent follow ups for its modifications which is required as the infant grows. (2 of our cases discontinued its use in 3rd month of life.)
2. Oral ulceration, which is a common known side effect of obturator application.⁽³⁸⁾
3. Small sample size.

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Photograph No. 1 Isolated left cleft lip



Photograph No. 2 Unilateral combined cleft palate and lip



Photograph No. 3 Bilateral combined cleft palate and lip



Photograph No. 4 A case of isolated right cleft lip with weight > 5th percentile



Photograph no. 5 A case of unilateral combined left cleft palate and lip with weight < 5th percentile



Photograph no. 6 A case of bilateral combined cleft palate and lip with obturator in situ

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