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Effect of Micronutrient-Fortified Malt on Body Iron Stores and Growth in Infants with Cleft Lip and Palate: A Randomized Controlled Trial

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Abstract:

Background: Infants with cleft lip and palate (CLP) face significant nutritional challenges, leading to undernutrition, growth faltering, and iron deficiency anemia (IDA), which can delay crucial surgical interventions. This randomized controlled trial aimed to evaluate the effect of a micronutrient-fortified malt intervention on body iron stores and growth in infants with CLP.

Methods: A randomized controlled trial was conducted at a tertiary care hospital in Belagavi, India. Infants aged 5-7 months with CLP were randomized (1:1) to receive either micronutrient-fortified malt or unfortified malt and nutrition education for six months. Primary outcomes included hemoglobin, serum ferritin, serum iron, serum transferrin, total iron binding capacity, and serum zinc. Secondary outcomes assessed growth parameters (WAZ, WLZ, HAZ). Data were collected at baseline (lip surgery) and endpoint (palate surgery) and analyzed using appropriate statistical tests.

Results: Ninety-eight mother-infant pairs completed the study (control n = 48, intervention n = 50). At palate surgery, the intervention group showed statistically significant improvements in hemoglobin (p=0.004), serum transferrin (p=0.034), and serum iron (p=0.016) compared to the control group. Serum zinc levels did not differ significantly between groups (p=0.195). The prevalence of IDA in the intervention group was lower than in control group (12.0% vs. 27.1%); however, the difference was not statistically significant (p = 0.059).

While macronutrient intake was comparable, the intervention group had significantly higher intake of iron, zinc, and vitamin C (p=0.001 for all). Short term malnutrition status improved for weight for Age Z – Score (p=0.009), but chronic malnutrition indicators (HAZ and HCZ) worsened in both groups, indicating persistent long term growth deficits.

Conclusion: Micronutrient-fortified complementary feeding significantly improved iron status and acute nutritional outcomes in infants with CLP during the perioperative period. Integrating nutrient-dense, locally acceptable complementary food with feeding support and caregiver education can enhance nutritional recovery and surgical readiness, though long-term growth deficits require further investigation.

Trial Registration: The trial is registered on 23rd November 2022 with Clinical Trials Registry of India (CTRI/2022/11/047579).

Keywords: Cleft lip and palate; Micronutrient fortification; Iron deficiency anemia; Infant nutrition; Fortified malt; Cleft repair surgery.

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Author's Contribution:

KVU, RSP, RMB, MG - conception **OR** design of the work

KVU - acquisition of data

KVU, AC, ABN -analysis, interpretation of data and writing of manuscript.

KVU, RSP, RMB, MG, AC, ABN have reviewed manuscript.

Background:

In India, incidence of cleft lip and palate (CLP) is nearly 35,000 annually making it a major public health concern.[1] The CLP deformity leads to substantial feeding challenges mainly due to the deficit in the palate and to a lesser extent due to the discontinuity in the lip. The first 1000 days of life represent a critical window for growth and development, during which optimal nutrition is essential particularly for infants born with this deformity.

Infants with CLP conditions can undergo timely surgical repair, provided they meet the prerequisites for surgery, namely the minimum required weight and hemoglobin level. The preferred age to repair lip is before 6 months and for cleft palate repair is 9–12 months. However, these procedures are often delayed due to malnutrition.[2] Feeding challenges, recurrent infections, surgeries, and low socio-economic conditions of the care givers worsen the nutritional status of these infants. Infants born with CLP represent a largely overlooked high-risk group for undernutrition, growth faltering and micronutrient deficiencies- particularly Iron Deficiencies Anemia (IDA).

IDA adversely affects physical growth, cognitive function and increases postoperative complications. Infants with CLP are especially vulnerable due to inadequate complementary feeding, increased nutritional demands associated with frequent infections, and post operative healing. Daily dietary iron requirement is often unmet as complementary feeds are poor sources of iron and food fortification is not widely practiced in India.[3,4] Any form of malnutrition can delay the necessary corrective surgery which is the key for optimal growth and development. [3- 10]

Several studies from different parts of India have reported high burden of anemia (74.6%, 83.16% and 89.9%) in this group.[7] These findings underscore the importance of early

nutritional assessment and targeted interventions to improve iron status prior to surgical repair. Nutrition interventions, such as education on Infant Young Feeding Practices (IYCF) [11] or through targeted nutritional supplementation can help maintain or improve nutritional status in this vulnerable group. IYCF a key element laid by WHO to address malnutrition, is sub-optimal in this vulnerable population owing to feeding challenges.[12] Existing studies on nutritional interventions focus on infants who have been ruled unfit for cleft repair, which inherently delays the timing of surgical interventions. [9,13]

Fortification ranks among the top high return investment for health and economic growth, as per Copenhagen Consensus Expert Panel (2008), especially beneficial when applied to staple foods.[4] A current approach to address malnutrition in this high-risk group is through micro nutrient fortified malt, which has been recognized as an effective and culturally accepted strategy to improve micronutrient intake and health outcomes in pediatric population. A millet-based complementary food fortified with iron, zinc and vitamin C has the potential to enhance iron absorption, improve body iron stores, and boosts immunity.[4,14-16] The postoperative care for infants with cleft lip and palate is unique since the procedures are performed in a very young age groups and involve multiple tissues types.[10] Supplementation during the period between the two primary cleft surgeries, which is the critical growth period may support nutritional recovery and improve surgical readiness. Alongside this intervention, structured counselling on nutrition and hygiene provided to caregivers will further improve health outcomes and surgical readiness.

Existing studies on nutritional interventions focus on infants ruled unfit for cleft repair, inherently delaying surgery. To our knowledge, no prior randomized trial has evaluated the effect of a micro nutrient complementary food on body iron stores and growth during the

planned inter- surgical period (between lip and palate repair) in all eligible infants. This study addresses that gap by providing a locally developed, fortified malt intervention during the critical complementary feeding window, with the goal of optimizing nutritional status and surgical readiness. We hypothesized that the intervention would result in a clinically significant increase in hemoglobin concentration (≥5 g/L) and improved growth parameters compared to the control group.

Methodology:

A randomized control trial was conducted to assess the effect of micro nutrient fortified malt on body iron stores and growth among infants with cleft lip and palate. The study was carried out between January 2023 to December 2025 at a tertiary care hospital in Belagavi, Karnataka, India providing comprehensive multidisciplinary cleft care. This randomized controlled trial was conducted and reported in accordance with the CONSORT 2010 Statement. A completed CONSORT 2010 checklist is provided as supplementary material.

Ethical Considerations: The study was approved by the KAHER Ethics Committee (Approval No: KAHER/EC/22-23/). Written Informed consent was obtained from all caregivers prior to enrolment. The study was conducted in accordance with the Declaration of Helsinki and registered with Clinical Trials Registry of India on 23rd November 2022 (CTRI/2022/11/047579).

Study Participants:

Inclusion Criteria:

1) Infants aged 5-7 months diagnosed with cleft lip and palate attending the outpatient department (OPD)

2) Caregivers willing to participate were included in the study.

Exclusion Criteria

1) Infants with isolated cleft lip only,

2) Syndromic clefts, and infants with other associated congenital anomalies were excluded from the study.

Sample Size: The sample size was calculated to detect a minimum increase of 5 g/L in hemoglobin concentration (primary outcome) with 80% power and a two-sided significance level of 10%. Standard deviations of 8.7 g/L and 10.2 g/L were obtained from previous studies. After allowing for a 10% loss to follow-up, the required sample size was increased to 50 infants per group. Secondary outcome (ferritin, growth parameter) was not powered separately. Therefore, a total of 103 infants were recruited for the study. The sample size was estimated using the formula:

$n = [(Z\alpha/2 + Z\beta)^2 (\sigma_1^2 + \sigma_2^2)] / d^2$ [16]

Randomization and Allocation Concealment: Eligible participants were randomized using a computer-generated random sequence in a 1:1 ratio to either intervention or control group. Allocation concealment was ensured using sealed sequentially numbered envelopes prepared by an independent researcher. Caregivers and outcome assessors including laboratory personnel and anthropometric assessors were blinded to group allocation. The sensory characteristics of the products were similar, with no significant differences observed (taste, smell, color) or any observable changes between fortified and unfortified malt and hence we could blind the caregivers.

Intervention: Study participants received either micronutrient fortified malt (Annexure 1) or unfortified malt (UM) for a duration of six months. Data collected at the time of lip surgery were considered the baseline, while data collected at palate surgery were considered the endpoint.

A daily dose of 25 g of fortified food was selected to provide approximately 75% of the Indian Recommended Dietary Allowance (RDA) for iron, zinc and vitamin C,[16] balancing the need to address documented micronutrient gaps in this population. The supplement was given in addition to infant's habitual diet. Caregivers were instructed to provide 25 g of supplement per day, divided into two servings for a duration of six months. The selected quantity (25 g) was considered age appropriate and practical for ensuring sustained compliance over the period.

Caregivers received detailed guidance on preparation, consistency modification, and feeding techniques suitable for infants with CL/P. Standardized measuring cups and spoons were provided to ensure right portion and consistency and these tools facilitated more reliable dietary recall. Both groups received routine nutrition counselling as per national Infant and Young Child Feeding (IYCF) guidelines. Regular monthly follow-up was maintained throughout the intervention period.

Data Collection:

At enrolment, maternal socio-demographics characteristics and infant's feeding practices were recorded using a pretested structured questionnaire.

Anthropometric measurements were recorded using standardized techniques and plotted on the WHO growth charts to assess nutritional status. Weight was measured using a calibrated digital infant weighing scale, length using an infantometer, head circumference

was measured using non stretchable tape and mid upper arm circumference was measured using a Shakir's tape. Each measurement was taken three times by the trained health care professional and the mean value was recorded at monthly visits.

Blood sample were taken at enrolment and at the end of the study to estimate hemoglobin, serum ferritin, serum iron, serum transferrin, total iron binding capacity and serum zinc.

Data collected at the time of lip surgery were considered baseline measurements, while data collected at palate surgery were considered endpoint measurements because the intervention was between two surgeries.

Follow Up and Monitoring:

Participants were followed monthly for six months to monitor growth, adherence to intervention, and adverse events. Dietary intake was assessed using the 24-hour dietary recall method. Daily intake of energy, macronutrients and selected micronutrients (iron, zinc, and vitamin c) from complementary food at 12 months of age was calculated using Indian Food Composition Tables.

Nutrition education was reinforced through counselling sessions. Education was reiterated using on WhatsApp messages including instructional videos on correct feeding practices. Caregivers were encouraged to share feeding videos for monitoring and correction of practices.

Dietary compliance was assessed primarily through caregiver interviews and 24 dietary recall. Empty malt packets were collected every month to ensure compliance. While we also monitored biochemical indicators such as hemoglobin, serum ferritin, as markers of intervention response.[17] Concomitant medications, including the use of iron supplements and other medications during the study were monitored.

Outcome Measures:

Primary outcome: Body iron stores - hemoglobin levels, serum ferritin, serum iron, serum transferrin, total iron binding capacity and serum zinc were measured at base line and at the end of the study.

Secondary outcomes: Growth was assessed using weight for age (WAZ), weight for length (WLZ) and height for age (HAZ).

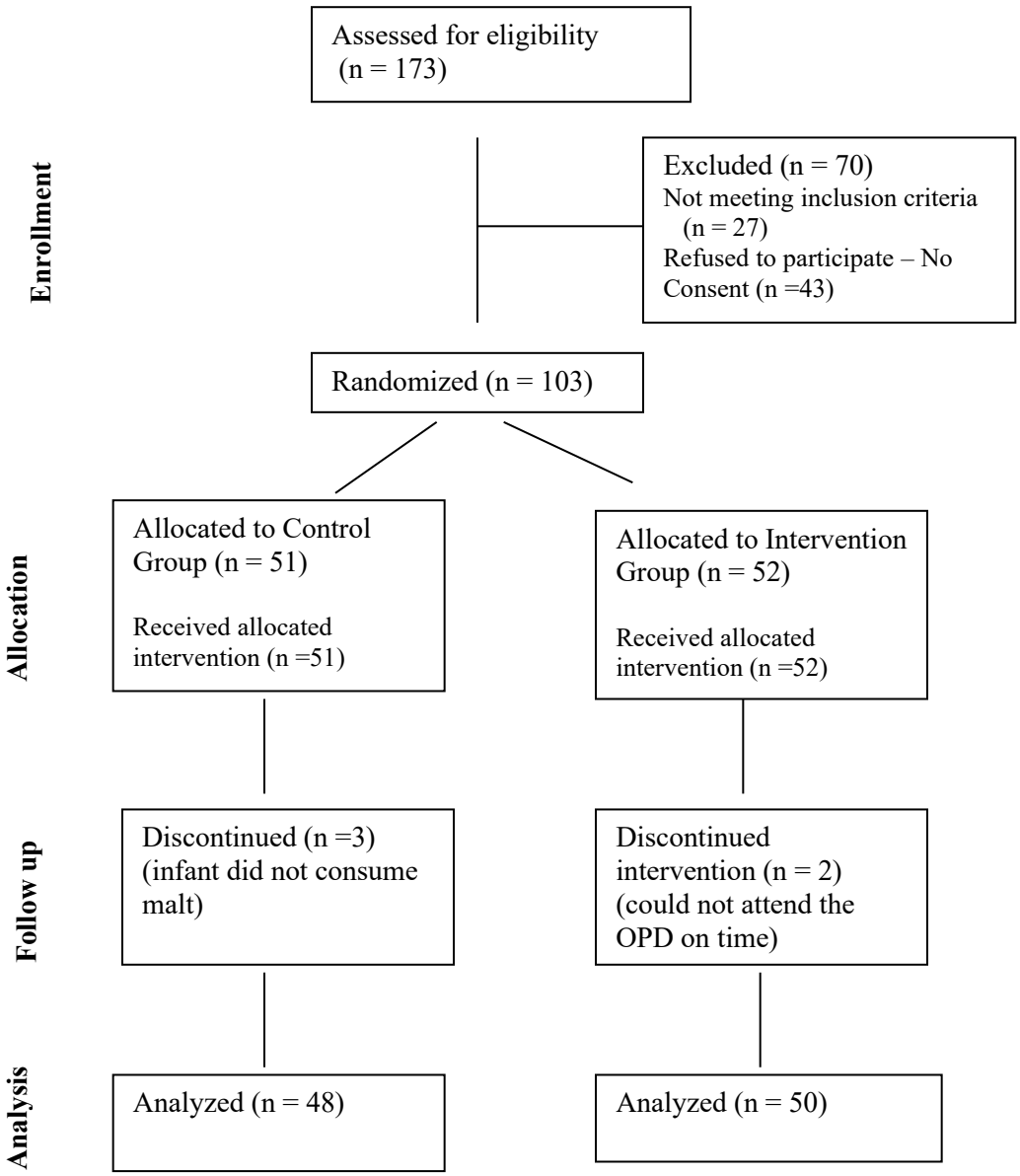
Adverse Events and Safety Monitoring:

All adverse events were monitored and recorded if any throughout the study period. Appropriate medical care was provided when required.

Statistical analysis:

Data was analyzed using SPSS version 29. Frequency and percentage were computed for categorical variables. Descriptive statistics mean and standard deviation were calculated for continuous variables. Normality of the data was assessed using Shapiro-Wilk tests. Association between variables was analyzed using the Chi-square test, paired t test and Wilcoxon Signed Rank test. Between group comparison was done using Mann Whitney U test or independent t test. A p-value less than 0.05 was considered statistically significant. Per protocol analysis was performed.

CONSORT diagram



Results:

Table1: Baseline characteristics of participants in the control and intervention groups.

Variables		Control (48)	Treatment (50)	Total (98)	p value
		n (%)	n (%)	n (%)	
Age group	18 - 25	25 (52.1)	31 (62)	56 (57.1)	0.321
	25 - 35	21 (43.8)	15 (30)	36 (36.7)	
	Above 35	2 (4.2)	4 (8)	6 (6.1)	
Education	Illiterate	1 (2.1)	7 (14)	8 (8.2)	0.198
	Primary	6 (12.5)	5 (10)	11 (11.2)	
	Secondary	29 (60.4)	27 (54)	56 (57.1)	
	Graduate	12 (25)	11 (22)	23 (23.5)	
Consanguineous Marriage	No	35 (72.9)	35 (70)	70 (71.4)	0.749
	Yes	13 (27.1)	15 (30)	28 (28.6)	
Religion	Hindu	34 (70.8)	46 (92)	80 (81.6)	0.023*
	Muslim	13 (27.1)	4 (8)	17 (17.3)	
	Christian	1 (2.1)	0 (0)	1 (1)	
BPL	BPL	41 (85.4)	42 (84)	83 (84.7)	0.846
	APL	7 (14.6)	8 (16)	15 (15.3)	
Family Type	Nuclear	10 (20.8)	13 (26)	23 (23.5)	0.546
	Joint	38 (79.2)	37 (74)	75 (76.5)	
Parity	One	17 (35.4)	17 (34)	34 (34.7)	0.666
	Two	17 (35.4)	23 (46)	40 (40.8)	
	Three	9 (18.8)	6 (12)	15 (15.3)	
	Four	5 (10.4)	4 (8)	9 (9.2)	
Term	Full term	47 (97.9)	48 (96)	95 (96.9)	0.582
	Pre-term	1 (2.1)	2 (4)	3 (3.1)	
Type of delivery	Normal	29 (60.4)	26 (52)	55 (56.1)	0.401
	C-section	19 (39.6)	24 (48)	43 (43.9)	
Cleft Diagnosed	No	13 (27.1)	15 (30)	28 (28.6)	0.749
	Yes	35 (72.9)	35 (70)	70 (71.4)	
Type of Cleft	Unilateral	32 (66.7)	38 (76)	70 (71.4)	0.124
	Bilateral	12 (25)	5 (10)	17 (17.3)	
	Only Palate	4 (8.3)	7 (14)	11 (11.2)	
Type of Diet	Veg	10 (20.8)	16 (32)	26 (26.5)	0.211
	Non-Veg	38 (79.2)	34 (68)	72 (73.5)	
Baby Gender	Female	19 (39.6)	19 (38)	38 (38.8)	0.872
	Male	29 (60.4)	31 (62)	60 (61.2)	
	< = 6 times	42 (87.5)	44 (88)	86 (87.8)	0.94

Number of follow ups	> 6 times	6 (12.5)	6 (12)	12 (12.2)	
Complications	None	37 (77.1)	37 (74)	74 (75.5)	0.404
	URI	10 (20.8)	9 (18)	19 (19.4)	
	GI	1 (2.1)	4 (8)	5 (5.1)	
Nutrition related admission	No admission	47 (97.9)	49 (98)	96 (98)	0.977
	Admission	1 (2.1)	1 (2)	2 (2)	

Note *- p value was computed using Chi-square test/ Fisher Exact test, (*) indicates statistical significance with value less than 0.05.*

Table 1 represents data of 98 mother infant pairs, with 48 in control group and 50 in intervention group. There were no statistically significant differences in the baseline characteristics between the groups except in religion (**0.023***). With 81% are from Hindu community indicating a largely homogeneous study population.

Table 2: Comparison of Hematological and Biochemical Parameters among Control and Intervention Groups at Lip Surgery and Palate Surgery.

Variables	**Lip Surgery**			**Palate Surgery**		
	Control	**Intervention**	**p value**	**Control**	**Intervention**	**p value**
	Mean ± SD	**Mean ± SD**		**Mean ± SD**	**Mean ± SD**	
Haemoglobin	10.66 ± 1.16	10.77 ± 0.93	0.333	10.09 ± 1.24	10.94 ± 1.07	0.001*
Serum Ferritin	44.53 ± 32.32	47.95 ± 41.84	0.76	33.59 ± 43.47	49.79 ± 51.28	0.035*
Serum Transferin	11.44 ± 7.07	11.94 ± 5.52	0.347	8.5 ± 5.79	16.86 ± 10.37	0.001*
Serum Iron	38.99 ± 21.56	40.24 ± 16.64	0.473	29.46 ± 16.71	44.94 ± 25.81	0.001*
TIBC	366.1 ± 60.72	357.32 ±92.01	0.491	404.19 ± 88.7	354.62 ±89.18	0.001*
Serum Zinc (#)	124.98 ±37.02	114.79 ±31.43	0.145	121.62 ±26.06	129.76 ±34.86	0.195

Note *- p value was computed using independent t test (#) and Mann Whitney U test, (*) indicates statistical significance with p value < 0.05*

Table 2 compares body iron stores and zinc levels at lip and palate surgery among control and treatment groups. The intervention began after lip surgery and continued for six months up to palate surgery. At the time of palate surgery, there was statistically significant

improvement in all body iron stores parameters in intervention group while in the control group, there was decreased levels of the same parameters. In the control group, elevated TIBC typically reflects iron deficiency, suggesting worsening iron status. There was no difference in serum zinc among both the groups following the intervention. At 6 months, the prevalence of iron deficiency anemia among infants with cleft did not differ significantly between the control and treatment groups (8.3% vs. 10.0%; p = 0.775). At 12 months, infants with cleft in the treatment group showed a lower prevalence of iron deficiency anemia compared with those in the control group (12.0% vs. 27.1%); however, the difference was not statistically significant (p = 0.059).

Table 3: Comparison of Mean Change in Anthropometric and Biochemical Parameters between Control and Intervention Groups.

Variable	Control	Intervention	p value
	Mean ± SD	Mean ± SD	
Weight	1.9 ± 0.91	2.03 ± 0.85	0.506
Length	8.72 ± 8.74	8.25 ± 7.9	0.849
Head C	1.95 ± 1.4	2.51 ± 3.99	0.836
MUAC	0.6 ± 1.23	0.69 ± 1.02	0.681
Hb	-0.57 ±1.48	0.17 ± 0.87	0.003*
S. Ferritin	-10.93 ± 31.85	1.83 ± 28.29	0.001*
S. Transferin	-2.94 ± 7.94	4.92 ± 7.74	0.001*
S. Iron	-9.52 ± 19.75	4.7 ± 20.05	0.001*
TIBC	38.08 ± 69.77	-2.7 ± 91.67	0.001*
S. Zinc	-3.36 ± 31.87	14.97 ± 31.7	0.001*

Note *- p value was computed using Mann Whitney U test, (*) indicates statistical significance with p value < 0.05*

Table 3 presents the mean change in anthropometric and biochemical parameters between the control and intervention groups. The nutritional intervention significantly improved the biochemical parameters but had little impact on the anthropometric parameters.

Table 4: Comparison of Dietary Nutrient Intake among Control and Treatment Groups.

Variables	Control	Intervention	p value
	Mean ± SD	Mean ± SD	
Calories	855 ± 56.87	854.4 ± 55.7	0.989
Proteins	17.79 ±2.44	18.38 ± 2.78	0.395
Fat	19.23 ±2.93	18.92 ± 2.51	0.601
Iron	4.4 ± 0	6.75 ± 0	0.001*
Zinc	4.3 ± 0	6.87 ± 0	0.001*
Vitamin_C	10 ± 0	30 ± 0	0.001*

Note - p value was computed using independent t test (#) and Mann Whitney U test, (*) indicates statistical significance with p value < 0.05

Table 4 represents the comparison of mean nutrient intake among control and treatment groups. There was no statistically significant difference between the groups in terms of macronutrient intake. However, the treatment group demonstrated significantly higher micronutrient intake compared to the control group. The mean dietary intake of iron, zinc and vitamin c was significantly higher in the treatment group compared to the control group. These findings indicate that while macronutrient intake remained comparable between groups, the intervention significantly improved the intake of key micronutrients, like zinc, iron, and vitamin C.

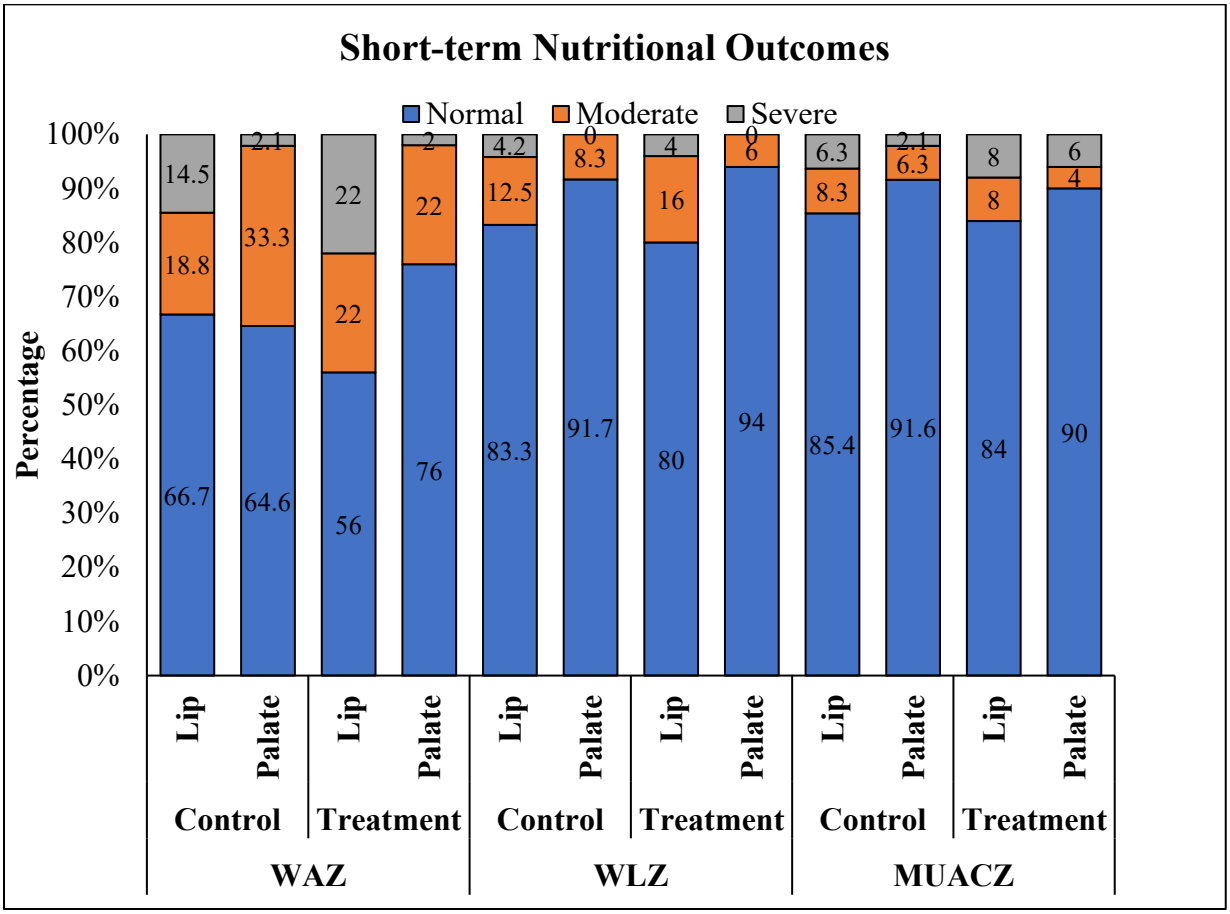
Table 5 - Surgical Timing (On-Time vs Delayed) for Palate Repair among Control and Treatment Groups.

Surgery	Time	Control		Intervention		p value
		n	%	n	%	
Palate	Ontime	29	60.4	32	64	0.715
	Delayed	19	39.6	18	36	

Note - p value was computed using Chi-square test, (*) indicates statistical significance with p value < 0.05

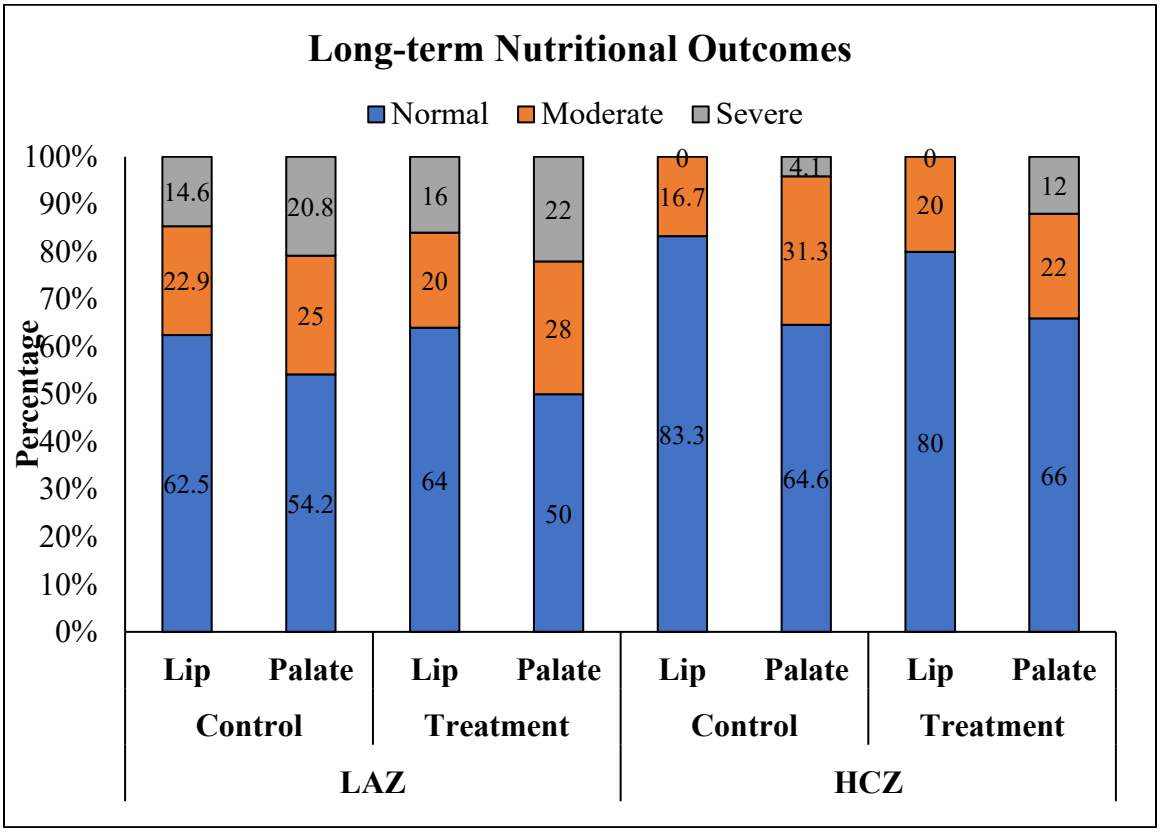
Table 5 compares the proportion of infants who underwent palate surgery on time versus delayed among the control and intervention groups. There was no statistically significant difference in the timing of palate surgery between the groups following the intervention. The mean age (in months) at which infants in control group underwent palate surgery on time was 13.02 ± 1.87 and for intervention group was 12.76 ± 1.48

Graph-1 Comparison of Short-Term Nutritional Outcomes among Treatment and Control group at Lip and Palate Surgery.



Graph 1- Comparison of the Short-Term Nutritional Outcomes among treatment and control groups revealed a significant difference in Weight-for-Age Z-score (WAZ) distribution (p = 0.009), with a higher proportion of normal-weight infants and fewer severely underweight infants in the treatment group. In contrast, Weight-for-Length Z-score (WLZ) and Mid-Upper Arm Circumference Z-score (MUACZ) distributions were comparable between groups, with the majority of infants classified as normal. No significant difference was observed for MUACZ (p = 0.362), while statistical testing for WLZ was not feasible due to the absence of severe wasting in some categories.

Graph -2 Comparison of Long- Term Nutritional Outcomes among Treatment and Control group at Lip and Palate Surgery.



Graph 2 shows worsening of Long-Term Nutritional Outcomes among treatment and control group from lip to palate surgery as measured by length for age and head circumference for age indicating long term growth deficits.

Adverse Event Reporting - Upper respiratory tract infections were the most commonly reported adverse events, affecting 20.8% of participants in the control group and 18.0% in the intervention group. Gastrointestinal infections were reported in 2.1% and 8.0% of participants in the control and intervention groups, respectively. All cases were managed by the pediatrician. Two participants, one from each group, required hospitalization, and no intervention-related adverse events were observed.

Discussion:

The present study assessed the effect of a micronutrient fortified malt on body iron stores and growth among infants with cleft conditions during the period between lip and palate surgeries. This highlights the importance of early nutritional intervention in optimizing nutritional outcomes in infants with CLP. The intervention has improved both circulating iron indicators and body iron stores.

The improvement observed in the treatment group was because of fortified millet-based malt which provided 75% of the RDA. This likely bridged the dietary gap, enhanced nutrient density and improved micronutrient intake without altering macronutrient consumption. Some plausible reasons for the intervention to be effective are combination of locally available millets and pulses which improved the micronutrient profile. In addition to their micronutrient density, millets contain substantially higher dietary fiber than refined cereals, which may support improved gut health. Secondly, processing methods like roasting, dehulling and germinating, are known to reduce phytate content in

cereals, which could enhance iron and zinc bioavailability. Furthermore, the inclusion of vitamin C in the fortified malt likely enhanced non-heme iron absorption, thereby improving iron utilization and contributing to better iron status among infants in the treatment group. [4,15,16]

The present study results align with World Health Organization (WHO) meta-analysis showing that rice fortified with iron reduced IDA by 35% and increased average haemoglobin concentration by nearly 2 g/L. Iron Fortification studied in 13 trials reported improvement in haemoglobin and serum ferritin. Several studies have demonstrated that fortified complementary foods can mitigate micronutrient malnutrition and improve growth and development in children.[4,14,16] On the contrary, a study conducted in rural Burkina Faso with multiple micronutrients supplement had no additional effect on Hb concentration, which the authors attributes to low bioavailability of minerals in the cereal used.[15]

Short term nutritional outcome as assessed by weight for age, weight for height and mid upper arm circumference showed improvement by the time of palate surgery whereas long term nutritional outcome such as height for age and head circumference showed higher proportion of severe deficits, indicating long term growth hampering in both the groups.[18] Weight gain was slightly higher in the treatment group at palate surgery, this near-significant finding could be clinically relevant, particularly in populations vulnerable to malnutrition, and may warrant further investigation with a larger sample size to improve statistical power. Worsening HAZ, implying that the intervention had limited influence on linear growth and HCZ, which are typically reflective of longer-term nutritional outcome. Linear growth faltering in children with cleft is multifactorial, involving not only nutrient

intake but also recurrent infection, early feeding challenges and potentially genetic or hormonal factors. A nationwide cohort study in South Asia demonstrated that children with cleft lip and palate experienced impaired general growth. [18]

Participants of both the groups had a similar dietary intake in terms of macronutrients but the treatment group had higher dietary intake of iron, zinc, and vitamin C through fortified malt. The higher dietary intake of iron and vitamin C in the treatment group is particularly relevant, as vitamin C enhances non-heme iron absorption, thereby improving iron bioavailability. This explains the significant improvements observed in body iron stores, demonstrating a direct association between dietary intake and biochemical outcomes. Increased dietary zinc intake may have contributed to improved immune function, however its biochemical impact was not statistically significant.

Although surgical timing was not a predefined study objective, it was analysed as an exploratory outcome. No statistically significant difference was observed in the timing of palate surgery between the treatment and control groups. We hypothesized that improvement in nutritional status following nutritional intervention could facilitate timely palate repair, as nutritional recovery is an important prerequisite for surgery readiness in infants with CLP. Surgical timing is likely influenced by multiple factors, including nutritional status and other non-nutritional factors such as intercurrent illness, access to care, and surgical logistics.[9,13] To the best of our knowledge, there is limited literature evaluating factors influencing surgical timing in this population. Further studies with larger sample sizes are needed to specifically assess the relationship between acute malnutrition and timing of palate surgery.

The results observed in treatment group reflects improvement in body iron stores and short-term nutritional outcomes, suggesting that the nutritional intervention had effectively addressed immediate nutritional needs. Infants with moderate malnutrition often have greater physiological requirements for nutrients to support catch-up growth, which could partly explain the observed response to the intervention. Infants with CLP have higher requirement for both energy dense and protective nutrients to replenish depleted tissues and then support catch up growth. [5,7,10,12,19,20] Furthermore, surgical intervention, increases nutrient demands during the postoperative period. Poor perioperative nutrition has been known to be associated with higher complication rates in various other surgical intervention.[15] In addition, orofacial surgery impairs postoperative feeding until the surgical site heals.[10]

Overall, these findings suggest that while the nutritional intervention had a limited impact on short-term anthropometric gains, it was effective in improving biochemical indicators of iron status. This supports the role of micronutrient-fortified interventions in addressing hidden hunger and anaemia, even when measurable changes in growth parameters are not immediately evident. The results highlights that biochemical recovery may precede observable anthropometric improvements, emphasizing the importance of early and sustained nutritional interventions in vulnerable paediatric populations.

The fortified food likely enhanced the intake of essential nutrients, particularly iron and other micronutrients, while nutrition education may have improved caregivers' knowledge and feeding practices. Together, these factors could have contributed to improved dietary quality, better nutrient utilization, and consequently improved nutritional and biochemical outcomes in the treatment group.

Globally, nutritional interventions such as feeding technique education, nutritional supplements, assistive feeding devices, and caregiver educational support programs have been implemented to improve the nutritional status of infants and ensure their eligibility for surgical repair. These evidences suggest that interventions are effective in addressing acute malnutrition, however their impact on long term growth outcomes remains limited. [9,13]

Strengths and Limitations:

This study has several strengths. It incorporated a planned nutritional intervention across two important surgical timepoint allowing for continuous nutritional support and perioperative assessment. The intervention used a locally developed, micronutrient-fortified complementary food, supporting accessibility, affordability and acceptability. The study emphasised on multidimensional nutritional status evaluation.

This study also has limitations. A six-month study duration was sufficient to assess short term outcome but inadequate for evaluating long term outcomes. Key inflammatory or infection markers (e.g., C reactive protein) that could influence ferritin levels were not assessed which may have contributed to elevated ferritin levels, potentially overestimating body iron stores in some participants.

Implications:

To our knowledge, this is one of the first randomized trial to demonstrate that a locally developed, micronutrient fortified complementary food can significantly improve iron status and acute nutritional outcomes during the inter-surgical period in infants with cleft conditions. The findings strongly advocate for the inclusion of nutrition education and fortified complementary food within routine cleft care to improve nutritional status and

enhance surgical readiness. The use of locally available formulations supports the accessibility, affordability in resource limited settings.

Conclusion:

This study outlines that micronutrient fortified complementary feeding improves iron status and short-term nutritional outcome among infants with cleft conditions during critical perioperative period. Our findings highlight that integrating nutrient dense, locally acceptable complementary food with structured feeding support and care giver education can enhance nutritional recovery and surgical readiness. While the intervention showed limited impact on long-term growth deficits, the observed improvements in biochemical markers underscore the potential of targeted nutritional strategies to address hidden hunger and anemia in this vulnerable pediatric population. These results advocate for the inclusion of such nutritional interventions within routine cleft care protocols, particularly in resource-limited settings.

Abbreviations:

CLP - Cleft lip and palate

IDA - Iron deficiency anemia

WAZ – Weight for Age Z Score

WLZ – Weight for Length Z Score

HAZ – Height for Age Z Score

HCZ – Head Circumference for Z Score

MUACZ – Mid Arm Upper Circumference Z Score

IYCF – Infant Young Child Feeding

WHO – World Health Organization

OPD – Out Patient Department

RDA- Recommended Dietary Allowance

TIBC – Total Iron Binding Capacity

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