CALCAREA PHOSPHORICA 30 A HOMOEOPATHIC MEDICINE AS AN ADJUVANT IN MALNUTRITION ASSOCIATED WITH VITAMIN-D DEFICIENCY IN THE AGE GROUP 1-6 YEARS: A RANDOMISED CLINICAL STUDY

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ABSTRACT: Malnutrition is a major public health issue for under-five children and is a leading cause of child mortality. In developing regions, its widespread impact is often concealed, akin to an iceberg. Vitamin D deficiency, a key micronutrient, impairs growth and development thereby impacting 31-61% of malnourished children globally.

OBJECTIVE: To determine the effectiveness of homoeopathic medicine *Calcarea Phosphorica* 30 as an adjuvant in cases of malnutrition associated with Vitamin-D deficiency in children between 1- 6 years age group

METHODS: The research is a single blind, randomised clinical trial. A total of 33 patients (Experimental/*Calcarea phosphorica* 30= 17, Control/Placebo 30=16; drop out=3) of malnutrition associated with Vitamin-D deficiency were enrolled and randomised by coin flip technique. Primary and secondary outcome measurements were used to assess the changes in anthropometric measurements and lab parameters (Vit-D, CBC, serum calcium and serum albumin) respectively. IAP and WELLCOME classification were also evaluated to validate the improvements in patients.

RESULTS: The experimental group demonstrated significant improvements in anthropometric measurements and a substantial increase in Vitamin D levels (75.8%) indicating the effectiveness of the intervention. The data undeniably illustrates notable improvements in malnutrition grades as per IAP classification and a remarkable improvement (78.57%) of patients from undernourished to well-nourished category as evidenced by the WELLCOME classification. These compelling findings decisively support the recommendation of *Calcarea Phosphorica* 30 as an adjuvant in addressing malnutrition associated with Vitamin D deficiency.

CONCLUSION: Thus, a noteworthy improvement was noted by using Calcarea *Phosphorica* 30 as an adjuvant in malnutrition associated with vitamin-D deficiency in children aged 1 to 6 years.

KEYWORDS: Malnutrition; Vitamin-D deficiency; Calcarea Phosphorica; Undernutrition

1.0 INTRODUCTION:

Malnutrition is like an iceberg; wherein the majority of people in developing countries live under this burden.[1] According to the 2020 Global Hunger Index, India is classified as having 'serious hunger' with 14% of the population being undernourished.[2] Paediatric malnutrition (undernutrition) occurs when there is an imbalance between dietary intake and nutritional needs. This imbalance can result in cumulative deficits of calories, protein, or micronutrients, negatively impacting growth, development, and other relevant outcomes.[3] It includes stunting, wasting, low birth weight, restricted intrauterine growth, and micronutrient deficiencies.[4] Deficiencies in five important micronutrients (vitamins A and D, iron, zinc, and iodine) contribute to about 12% of global mortality among children of under 5 years of age.[4] The incidence of Vitamin D deficiency in malnourished children is estimated to be between 31% and 61% worldwide.[5] Rana R Mokhtar et al., in their cross-sectional study, concluded that underweight children had lower levels of blood 25-hydroxyvitamin D (25(OH)D) (<42.5 nmol/l) than normal-weight children. Furthermore, serum 25(OH)D levels less than 42.5 nmol/l were highly related to stunting in children.[6] Similarly, Ikram Hussain et al. also identified a clear link between malnutrition in children and vitamin deficiencies.[7] Another study conducted by Nahida Z. Walli et al, also stated that VDD (Vitamin-D deficiency) is quite prevalent in malnourished children which requires active surveillance and proper management.[8] Furthermore, Meret Merker et al. in their multicentre, pragmatic, open label study highlighted that Vitamin D deficiency is prevalent among malnourished inpatients and is linked to higher long-term death rates, especially when patients are not treated with vitamin D.[9] Adequate intake of those deficient micronutrients improves the linear growth and motor development, reduces anaemia and improves functional status in preschool and school-going children.[4]

The compelling report on WHO 2020 underscores the urgent need to address the critical challenges faced by millions of children under the age of five. Approximately 144 million children suffer from stunted development, while 47 million are affected by wasting and 14.3 million experience severe wasting.[10] These distressing statistics from the National Family Health Survey (NFHS)-5 for 22 states and union territories demand immediate attention to combat the issue of malnutrition.[2] Furthermore, the alarming prevalence of Vitamin D deficiency affecting 50-90% of Indian children calls for decisive action to safeguard their health and well-being.[5]

Vitamin D which is a prohormone plays an important role in bone mineralization. It has long-term advantages such as improved growth, lower risk of infections and promotes bone formation in LBW (low birth weight) babies.[11] Vitamin D deficiency can lead to severe wasting in malnourished children, whereas supplementation has been proven to improve weight gain in LBW newborns.[12] Dietary calcium and vitamin D deficits can negatively impact growth and development, even before rickets emerge.[13] Javeria Saleem et al. in their double-blind randomised placebo-controlled research concluded that high-dose vitamin D3 improved mean weight-for-height or -length z scores and developmental indicators in children receiving conventional treatment for uncomplicated severe acute malnutrition.[12] Similarly, Maurya M et al. also concluded that the study concluded that vitamin D supplementation lowers wasting on follow-up, indicating that it plays a key role in the long-term management of children with severe acute malnutrition.[5]

According to the statistics of the WHO, homoeopathy is the second most useful healthcare system in the world.[14] But after a thorough literature search it was found that a limited number of researches were conducted on malnutrition but those that were done showed positive results. A study done by Dr CHINCHU. G. S et al. showed that constitutional homoeopathic medicine

was effective in treating low growth and weight in children.[15] Another study done by Dr. F.F. Motiwala et al. revealed that homoeopathic medications when used in conjunction with diet can effectively help PEM (Protein energy malnutrition) children gain weight and increase their mid-arm circumference in comparison to conventional line of treatment.[16] Hardikkumar Tarunbhai Parikh et al. and Dr. Anjan Roy et al. concluded that homoeopathic treatment was effective in managing cases of malnutrition.[17,18] Apart from that it was observed that no research was conducted on malnutrition in association to Vitamin-D deficiency in spite of its higher prevalence.

The compelling evidence from the aforementioned studies using individualized homoeopathic medicine paves the way for further exploration. Therefore, a randomised controlled trial was done to determine the effectiveness of homoeopathic medicine *Calcarea Phosphorica* 30 (CP 30) as an adjuvant in cases of malnutrition associated with vitamin-D deficiency in children between 1-6 years age group

Hypothesis:

Homoeopathic medicine *Calcarea phosphorica* 30 as an adjuvant is effective in malnutrition associated with Vitamin-D deficiency in children between 1- 6 years age group.

Objective-

- **Primary objective:** To assess the effects of homoeopathic medicine *Calcarea Phosphorica* 30 as an adjuvant in changing the anthropometric measurements in children between 1-6 years age group suffering from malnutrition associated with vitamin-D deficiency.
- **Secondary objective:**

- To assess the change in the lab parameters (CBC, Vitamin-D, Serum calcium, Serum albumin) in children between 1-6 years age group suffering from malnutrition associated with vitamin- D deficiency.
- To assess the progress of the children between 1-6 years age group suffering from malnutrition associated with vitamin-D deficiency using IAP classification.

2.0 MATERIALS AND METHODS:

2.1 Study design and setting:

A randomised, single blind, clinical trial for malnutrition associated with Vitamin-D deficiency patients was conducted from February 2023 to April 2024. The Institutional Ethics Committee approved the study protocol. The study was registered under the Clinical Trial Registry of India (CTRI) with registration number CTRI/2023/02/049943. Written informed parental consent of all the patients was obtained prior to their children's participation in the study. Data collection was conducted by the investigator in accordance with the study protocol. A consultant Paediatrician was engaged at the centre to assess the cases in both groups.

2.2| Participants:

Case definition: All cases diagnosed with Grade I, Grade II, and Grade III malnutrition associated with Vitamin- D deficiency as per IAP classification in paediatric age group between 1 to 6 years irrespective of both the gender.

The study inclusion criteria consisted of patients 1) Satisfying the case definition were included for the study; 2) Patients were taken irrespective of socio-economic status; 3) Children under allopathic treatment for vitamin D deficiency were included in the study.

Cases were considered excluded where 1) Case did not fulfil the case definition; 2) Patients who need emergency medical intervention with complications of other systemic disease were

excluded; 3) Cases having severe acute malnutrition; 4) Cases diagnosed as Grade-IV (very severe malnutrition) as per IAP classification; 5) Cases diagnosed with tuberculosis; 6) Cases diagnosed with rickets and increased alkaline phosphatase were be excluded.

2.3 Randomisation: All enrolled patients were allocated into the treatment group (*Calcarea Phosphorica* 30/ CP 30) or control group (Sac lac 30/ SL 30) by coin flip technique.

2.4 Intervention:

Medicines were manufactured by a Good Manufacturing Practice certified homoeopathic pharmaceutical company and meticulously prepared in adherence to the guidelines of the Homoeopathic Pharmacopoeia of India were used in trial. Medicines in all forms and placebo (Rubrum or Sac lac) were dispensed in a setting that complies with Good Clinical Practice standards. Each dose was administered orally either medicine (*Calcarea phosphorica* 30) or placebo (Rubrum 30/Sac lac 30). Vitamin-D, as a supplement, was given to both groups by the paediatrician.

-Treatment group: Patients randomised to the treatment group received *Calcarea phosphorica* 30 (3 pills once every 15 days) and Rubrum 30 (3 pills OD) was continued every day for 6 months along with proper diet.

-Control group: Similarly, patients randomised to the control group received Sac lac 30 (3 pills once every 15 days) and Rubrum 30 (3 pills OD) was continued every day for 6 months along with proper diet.

2.5 Examination and investigations: The height, weight, mid arm circumference, head circumference and chest circumference was measured using a standardized weighing machine and measuring tape at each follow up. Also, the investigations conducted before the enrolment of patients were CBC (Complete blood count); Vit-D (Vitamin-D); Serum calcium; Serum albumin; Serum alkaline phosphatase [to rule out rickets] and after the intervention CBC; Vit-D; Serum calcium; Serum albumin to assess the changes in laboratory parameters.

2.6 Outcomes: The outcome assessment was done by:

- Calculating the anthropometric measurements before and after the course of treatment.
- Comparison and evaluation of the changes in the lab parameters (CBC, Vitamin-D, Serum calcium, Serum albumin) pre and post study of both the groups.
- Improvement of the patients with reference to the IAP classification and WELCOME TRUST classification.

2.7| Statistical methods: The data was analysed using a one-way ANOVA followed by least significant difference (LSD) test to differentiate the effect of different treatments at the probability level of $p < 0.05$ using SPSS v. 16.0. Additionally, F-statistics was conducted to observe the significance in the study of weight, height and chest increment before and after the intervention of drug. Furthermore, the significance of the Wellcome classification was investigated using 2-tailed statistics.

3.0 RESULTS:

3.1 Socio-demographic characteristics and outcome parameters:

Between February 2023 and April 2024, 100 patients were screened of which 33 were enrolled. Screening and enrollment were done followed by intervention and follow-up for the next six months [Fig I.] Out of these 100 screened cases, 67 were excluded due to various reasons as reflected in Fig I. There were 3 drop out of cases from the experimental group during the study. Therefore, out of 30 cases in total, 14 cases in experimental group and 16 cases in control group were considered for outcome analysis.

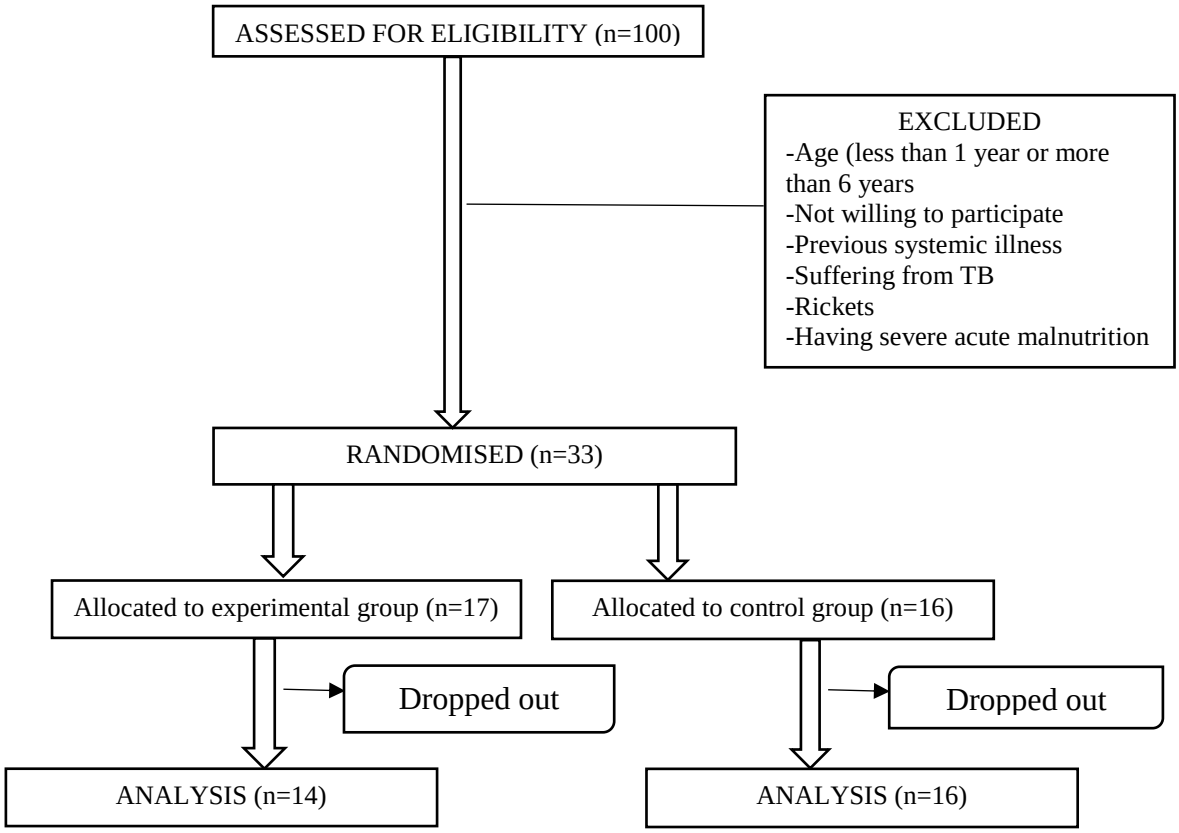

Fig I. CONSORT Study flow diagram

The baseline characteristics revealed that the experimental group consisted of 14 cases, with 3 (21.43%) being toddlers, 10 (71.43%) in early childhood, and 1 (7.14%) in middle childhood. Similarly, the control group comprised 16 cases, with 2 (12.5%) toddlers, 8 (50%) in early childhood, and 6 (37.5%) in middle childhood. Furthermore, the experimental group included 8 (57.24%) males and 6 (42.85%) females, while the control group had 5 (31.25%) males and 11 (68.75%) females. Additional demographic details, such as birth weight, mode of delivery, dietetic history, LSCS mode of delivery, dietetic history and FTND mode of delivery are outlined in Table I.

Table I. Baseline Characteristics:

BASELINE CHARACTERISTICS	Experimental Group		Control Group	
	n	%	n	%
SEX				
• Male	8	57.14	5	31.25
• Female	6	42.85	11	68.75
AGE				
• Toddler (1-2 years)	3	21.43	2	12.5
• Early childhood (3-5 yrs)	10	71.43	8	50
• Middle Childhood (more than 5 yrs-6yrs)	1	7.14	6	37.5

	n	%
BIRTH WEIGHT • < 2 kg • between 2-2.5 kg • > 2.5kg	 4 12 14	 13.33 40 46.67
MODE OF DELIVERY • LSCS • FTND	 14 16	 46.6 53.4
DIETETIC HISTORY AND LSCS • Formula milk • Breast fed	 6 8	 43 57
DIETETIC HISTORY AND FTND • Formula milk • Breast fed	 4 12	 25 75

3.2| Primary outcome:

The anthropometric measurements were carefully assessed during monthly follow-ups, encompassing a total of six measurements, including the initial registration and five subsequent follow-ups. The primary outcome data is presented in Table II. A significant improvement was observed in weight & height [Fig II], and chest circumference in the experimental group compared to the control group. However, no significant changes were noted in head circumference and mid-arm circumference in either group.

Table II: Primary outcome analysis in the experimental and control groups:

BASELINE CLINICAL DATA: (PRIMARY OUTCOME)					
Primary outcomes (Anthropometric measurements)		**Experimental Group**	**Control Group**	**P value**	**F statistics**
WEIGHT GAIN	**n (%)**	14 (10.39)	16 (4.44)	0.02	2.91
	Mean±SD (Before)	11.32±2.49	12.38±2.21		
	Mean±SD (After)	12.70±2.74	13.16±2.27		
HEIGHT INCREMENT	**n (%)**	14 (1.95)	16(0.65)	0.04	2.54
	Mean±SD (Before)	47.71±1.85	47.43±2.18		
	Mean±SD (After)	48.87±2.18	47.8±2.36		
CHEST CIRCUMFERENCE INCREMENT	**n (%)**	14 (1.96)	16 (0.7)	0.007	3.74
	Mean±SD (Before)	47.71±1.85	47.43±2.38		
	Mean±SD (After)	48.87±2.18	47.8±2.36		

3.2.1 Weight increment: The weight gain in CP intervened patients was observed to be significantly greater than SL intervened patients. The weight gain in the control patients were observed to be 16 (4.44%) whereas a substantial weight increment of 14 (10.39%) were noted

in the patients treated with *Calcarea Phosphorica* 30. The significance of the study attained from F statistics analysis has rejected the null hypothesis with a p-value less than 0.05. The bar diagram illustrating the distribution of weight gain among male and female patients in both SL and CP groups can be found in Fig II- 2 (a).

3.2.2 Height increment: The height increment in the CP intervened patients was observed to be significantly greater than SL intervened patients. The height increment in the control group were observed to be 0.65% whereas a substantial height increment of 1.95% was noted in the patients treated with *Calcarea Phosphorica* 30. The significance of the study attained from F statistics analysis has rejected null hypothesis with a p-value less than 0.05. The bar diagram illustrating the distribution of height gain among male and female patients in both SL and CP groups can be found in Fig II- 2 (b).

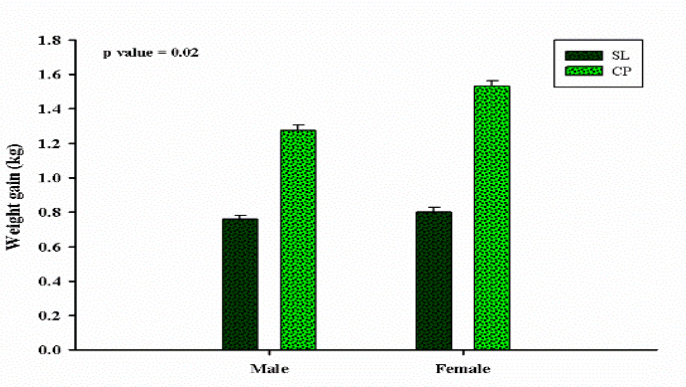

Fig 2(a): Weight increment

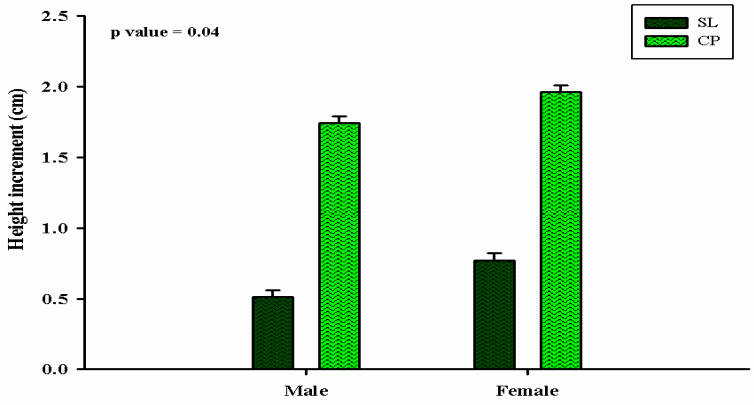

Fig 2(b): Height increment

Fig II. Bar diagram representing the increment of weight and height gain (anthropometric measurements) in both the groups

3.2.3| Chest circumference increment: The analysis of the increase in chest circumference (%) revealed highly significant findings. The control group displayed a chest circumference increase of 0.7%, while patients treated with *Calcarea Phosphorica* 30 showed a substantial increase of 1.96%. The calculated F statistic from the data was 3.74, with a mean square value of 1.708 between the groups, indicating noteworthy variance between the SL and CP intervention groups. Moreover, the achieved p-value of 0.007 underscores the considerable significance of the projected data [Table II above].

3.3 Secondary outcome:

The changes in lab parameters such as CBC, Vitamin-D, Serum calcium, Serum albumin was evaluated before and after the treatment. Significant changes in Vitamin-D and CBC were observed in both the groups but comparatively it was more the CP intervened group. However, no changes were observed in the Serum Calcium and Serum albumin levels as it was already in the normal range in all the patients. The IAP and WELLCOME TRUST classification was also assessed pre and post treatment to evaluate the improvement in the patients. The secondary outcome is illustrated in Table III.

Table III: Secondary outcome analysis in the experimental and control groups:

BASELINE CLINICAL DATA: (SECONDARY OUTCOME)					
Secondary outcomes		**Experimental Group**	**Control Group**	**P value**	**LSD**
VITAMIN-D	**Males (% increment)**	386.04	183.66	0.000	5.24
	Females (% increment)	252	206	0.000	2.56
	Mean±SD (Before)	19.31±7.10	24.39±5.47		
	Mean±SD (After)	79.89±8.26	72±6.44		
CBC	**Mean±SD (Before)**	11.60±0.72	11.35±0.74		
	Mean±SD (After)	12.77±0.53	12.63±0.42	0.01	0.97
WELLCOME CLASSIFICATION	**% undernourished (Before)**	100	100	0.000	1.25
	% well nourished (After)	78.57	37.5		
IAP CLASSIFICATION	**No improvement from Grade I**	8%	54%		
	Grade I to normal	92%	46%		
	No improvement from Grade II	0%	20%		
	Grade II to Grade I	100%	80%		

3.3.1| Vitamin-D levels: Paired t-test was conducted to witness the significance in the change in means between two paired observations (SL and CP) for both males and females. It was noted that the increment in the levels of Vitamin-D was more in males as compared to females in the CP intervened group [Fig III]. The results confirmed the data to be highly significant with a p-value of 0.000 and a least significant difference (LSD) of 5.24 for males and 2.56 for females [Table III above].

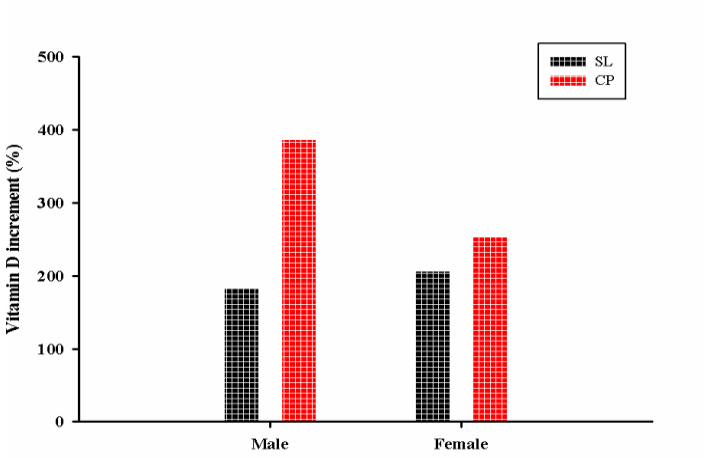

Fig III: Bar diagram representing the distribution of Vitamin-D increment in both Sac Lac and Calcarea Phosphorica intervened patients

3.3.2| CBC levels: A significant improvement was noted in the CBC values in both the SL and CP-intervened groups [Fig 4]. Based on the analysis, the null hypothesis is confidently rejected with a p-value of 0.01 and LSD of 0.97. The mean±SD before the treatment was noted to be 11.60±0.72 in experimental group and 11.35±0.74 in the control group. Similarly, after the treatment the mean±SD in experimental group was 12.77±0.53 and 12.63±0.42 in control group [Table III above].

3.3.3| Improvement in IAP classification: Improvement in IAP growth chart is an important indicator to examine the improvement in the grades of malnutrition. The study identified a 46% improvement in IAP from Grade 1 to normal and 80% improvement from grade 2 to grade 1 in SL. Additionally, 92% and 100% of improvements were observed in the CP-intervened group. Notably, all patients in the Grade 2 category were upgraded to Grade 1 in the CP intervention group; however, 20% of the patients showed no improvement from Grade 2 to Grade 1 in SL-treated samples [Fig, IV- 4 (a)]. Furthermore, the F statistics analysis conclusively rejected the null hypothesis with a p-value less than 0.05.

3.3.4| Improvement in WELLCOME TRUST classification: Wellcome classification is primary indicator to know the clinical type of PEM. The study depicted a significant transformation (78.57%) from undernourished to well-nourished patients for CP induced drug. However, only 37.5% of patients were recorded to be transformed to the well-nourished category in SL treated patients. The data is illustratively depicted in {Fig. IV- 4 (b). The paired T test undergone for the study represented a highly significant data with a p value of 0.000 and a least significant difference of 1.25 thereby rejecting the null hypothesis.

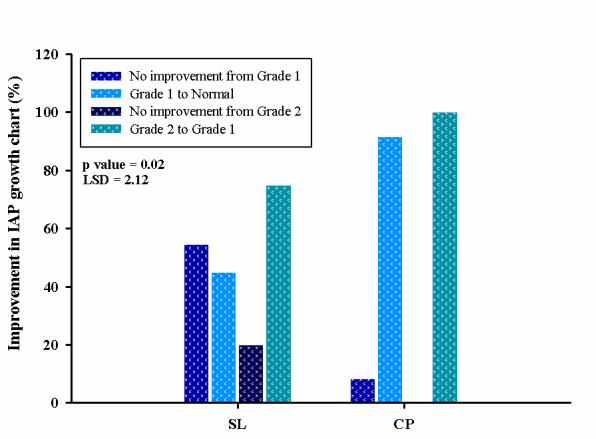

Fig 4 (a) IAP

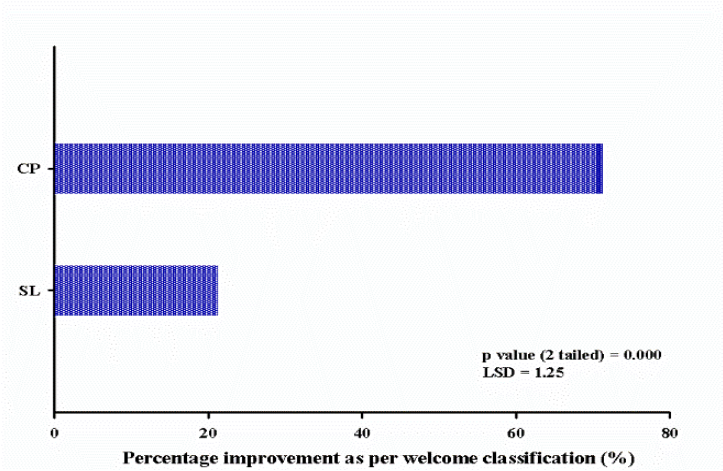

Fig 4 (b) WELLCOME TRUST

Fig IV. The bar diagram represents an improvement in grades of malnutrition as per IAP and WELLCOME TRUST classification

4.0 DISCUSSION:

Malnutrition continues to be a serious public health problem for children under the age of five as it is still the primary underlying cause of child mortality in many low and middle income countries.[10] As per the WHO 2020 report, around 144 million children under the age of five have stunted development, 47 million are wasted and 14.3 million are seriously wasted.[10] National Family Health Survey (NFHS)-5 statistics issued for 22 states and union territories show a concerning trend in malnutrition. The 2019-20 Sustainable Development Goals Index demonstrated a poor result on the Zero Hunger goal. According to the 2020 Global Hunger Index, India is classified as having 'serious hunger' with 14% of the population being undernourished.[2] Deficiencies in five important micronutrients (vitamins A and D, iron, zinc, and iodine) contribute to about 12% of global mortality among children of under 5 years of age.[4]

This single blind, randomised, placebo-controlled trial resulted in significant improvement of various parameters such as weight (P value = 0.02), height (P value = 0.04), chest circumference (P value = 0.007), Vitamin-D levels (P value = 0.000), CBC levels (P value = 0.01), IAP classification (P value < 0.05) and WELLCOME TRUST classification (P value =

0.000) in experimental group as compared to the control group in patients suffering from malnutrition associated with Vitamin-D deficiency.

Very few studies have been conducted in malnutrition using homoeopathic medicine as a therapeutic measure but those include only individualised homoeopathic medicine/deep acting medicines/constitutional homoeopathic medicine as an intervention.[15-20] After thorough search no studies were found that were conducted using single homoeopathic medicine in cases of malnutrition associated with Vitamin-D deficiency. But various stalwarts have mentioned in Homoeopathic Materia Medica literature that Calcarea phosphorica is effective in treatment of malnutrition as well as in patients having Vitamin-D deficiency.[21] It has lime and phosphorus as its main constituents so it is considered as an excellent remedy for poor nutrition.[22-24] It helps is malassimilation and its boosts ossification of bones.[23-25] It has also been mentioned that many children require this medicine during the growing phase due to its potential benefits.[26] Findings in this study correspond to literature, as a strong association of improvement was found by using *Calcarea phosphorica* 30 (homoeopathic medicine) as an adjuvant in cases of malnutrition associated with Vitamin-D deficiency.

Homoeopathic case taking holds a key aspect in considering the physical generals while evaluating the improvement in patients. So, while conducting the study it was also found that a significant improvement was seen in the appetite, thirst and there was reduced perspiration in most of CP intervened patients.

5.0 CONCLUSION:

Our findings indicate that use of the homeopathic medicine *Calcarea phosphorica* 30 as an adjuvant yields significant positive outcomes in addressing malnutrition associated with Vitamin-D deficiency in children aged 1-6 years. This approach may serve as a viable public health intervention in mitigating the escalating rates of malnutrition on a global scale. However, it is imperative to acknowledge the limitations of the study such as the small sample size and short duration. To solidify these promising outcomes, further research with a larger sample size and an extended study duration is imperative.

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