IJPSR (2023), Volume 14, Issue 7 **(Research Article)**

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 02 February 2022; received in revised form, 27 May 2023; accepted, 27 June 2023; published 01 July 2023

A COMMUNITY BASED STUDY TO EVALUATE THE EFFICACY OF CHATURJATADI SAMBHARAKA ON THE NUTRITIONAL STATUS OF CHILDREN WITH *BALSHOSHA* W.S.R. TO PROTEIN ENERGY MALNUTRITION

Vedprakash Meena * and Nisha Kumari Ojha

Department of Kaumarbhritya - Balroga, National Institute of Ayuveda, Jaipur - 302002, Rajasthan, India.

Keywords:

Balshosha, Deepana, Pachana, Brimhana, Protein energy malnutrition, *Chaturajatadi Sambharaka*

Correspondence to Author:
Vedprakash Meena

M.D. (Ayu.) Scholar,
Department of Kaumarbhritya - Balroga, National Institute of Ayuveda, Jaipur - 302002, Rajasthan, India.

E-mail: vedprakashmeena7706@gmail.com

ABSTRACT: Introduction: The aim was this trial is to assess to evaluate the effect of "*Chaturjatadi Sambharaka*" in the management of malnutrition in Children. **Material and methods:** This research work was done in two phases. Phase one included demographic study and in phase two was clinical study. A Randomized open label-controlled trial was conducted on100 undernourished children of 1-10 years of age group. Total cases were divided into two groups (50 in each). In Group A, only Nutritional Rehabilitation (As per ICMR guidelines) was administered whereas in Group B, Nutritional Rehabilitation (As per ICMR guidelines) along with the trial drug *Chaturjatadi Sambharaka* was administered. The trial drug was administered in *Avleha* form in a dose 180-200 mg/kg/day in divided dose or 8 weeks and post follow up was done after month. Scoring of chief clinical features was done before and after treatment. **Result:** The clinical efficacy of the drug was analysed statistically on all parameters mentioned in the Assessment criteria. Both groups, showed statistically significant ($P<0.001$) improvement on anthropometric parameters- Weight, Height, BMI, MUAC, SFT, and Chest circumference. However, on Intergroup comparison, group B showed statistically significant advantage over group A ($p<0.001$). The trial (Group B) showed significant improvement on laboratory investigations in Hemoglobin level, Total Serum Protein and A: G ratio ($p<0.001$). **Conclusion:** The trial group (Group B) which included *Chaturjatadi Sambharaka* along with nutritional rehabilitation was effective in the management of PEM/*Balshosha* due to its therapeutic and nutritional properties: *Deepana, Pachana, Balya, Brimhana,* and *Rasayana*.

INTRODUCTION: The term malnutrition includes both under nutrition as well as over nutrition and it is defined by low weight –for-age(underweight), length-for-age (stunting) or weight-for-length (wasting) [1]. Childhood under nutrition is widely recognized as major health problem in developing countries due to its disastrous consequences on development of child both physically and psychologically.

QUICK RESPONSE CODE

DOI: 10.13040/IJPSR.0975-8232.14(7).3596-10

This article can be accessed online on www.ijpsr.com

DOI link: https://doi.org/10.13040/IJPSR.0975-8232.14(7).3596-10

It is estimated that most of the children of preschool-age group are suffering from severe wasting. Under nutrition can be defined in children aged 6–59 months, as moderate wasting and/or mid-upper-arm circumference (MUAC) less than 125 mm^2. The most important element of our population is children, due not only to their sheer numbers, but also because the basis for adult life is built throughout these formative years.

Furthermore, these children will play a significant role in determining the quality of our future human resource. As a result, the well-being of these youngsters is critical to the country's development. The nutritional quality of children throughout their most susceptible and growing years builds the groundwork for excellent health in later years.

Studies on growth and physical development of infants and children are crucial determinants of health. At this age, malnutrition causes growth retardation, poor health, decreased efficiency, and a lower level of social production.

Many factors are responsible in the causation of malnutrition but poverty, unemployment, illiteracy, poor personal hygiene, low availability of health care facilities and inadequate food distribution system are the major factors of malnutrition. Malnourished children are more prone to systemic infection because Infections worsen malnutrition by reducing appetite, causing catabolism, and raising nutrient need. The level of weight loss and growth rate varies with the severity of PEM, *i.e.*, failure to maintain weight or growth rate in the early stages, but as the disease progresses, damage to the immune system occurs, which can lead to infection, shock, and death. Poor nutrition affects motor sensory, cognitive, social and emotional development. It is most deadly disease and may be called as "Silent killer" as it is associated with a wide variety of morbidities as their underlying cause in children. Malnutrition leads to ill health as well as poor immunity.

For the first time UNICEF, WHO and the World Bank reported joint estimates of child malnutrition for 2011. Estimates of prevalence and numbers for child stunting, underweight, and wasting are presented by United Nations, Millennium Development Goal, UNICEF, WHO regional and World Bank income group classifications. According to this estimate, in 2011, an estimated 165 million children under five years of age worldwide were stunted (low height for age below-2SD). High prevalence levels of stunting among children less than five years of age in Africa (36% in 2011) and Asia (27% in 2011). In 2011, an estimated 101 million children under five years of age worldwide were underweight (low weight for age below-2SD). Globally, an estimated 52 million children under five years of age were wasted (Weight for height below -2SD) in 2011. Seventy percent of the world's wasted children in Asia, most in South-Central Asia.

As per WHO assessment, in 2020, 47 million children under the age of five will be wasted, 14.3 million will be severely wasted, and 144 million will be stunted. In 2020, undernutrition will be responsible for almost 45 percent of fatalities among children mal the age of five. Low and middle-income countries are the most affected. The global burden of malnutrition has substantial and long-term developmental, economic, social, and medical consequences.

MATERIAL AND METHODS:

Study Type: A Randomized open label-controlled trial was conducted. The study was conducted under a strict protocol to prevent bias and to reduce the sources of error in the study.

Aim: To evaluate the effect of "*Chaturjatadi Sambharaka*" in the management of malnutrition.

Selection of Cases:

Source: Subjects attending the O.P.D and I.P.D. of Kaumarbhritya Department of National Institute of Ayurveda, Jaipur was screened for the present study.

Age Group: Children of 01 to 10 years of age were selected for the study.

Number of Cases: 100 cases (50 patients in each group).

Grouping of Cases: Total cases were divided into two groups.

Group A: 50 cases (Nutritional Rehabilitation)

Group B: 50 cases (Nutritional Rehabilitation + Trial Drug).

Criteria for Selection of Patients: All children within the age group 01 year to 10 years were subjected to detailed clinical examination and anthropometric measurement to screen out subjects suffering from varying degree of malnutrition according to the criteria as specified by Indian Academy of Paediatrics. A randomized study was conducted in children suffering from mild to moderate malnutrition.

Inclusion Criteria:

1. Children aged 01 year to 10 years of either sex suffering from mild-to-moderate degree of malnutrition with good appetite and no major complication (criteria as specified by IAP).

2. Mother and care taker trainable to provide home based diet.
3. Parents or caretaker willing to participate in the clinical trial.
4. Not planning to leave the study area for the coming 04 months.

Exclusion Criteria:

1. Children with age <01 year or age >10 year.
2. Children suffering from severe malnutrition (IAP criteria) with no appetite and complications, like Hypothermia, respiratory distress (presence of tachypnoea, intercostal recession), Extensive skin lesion/infection, lethargic, unconscious, Presence of convulsions, Severe dehydration based on history & clinical signs, Any condition that requires an infusion or NG tube feeding and Blood haemoglobin less than 06 gm/dl.
3. Tuberculosis
4. Cerebral palsy
5. Congenital heart diseases
6. Known metabolic disorders
7. Known mal-absorption syndromes
8. Chromosomal malformations
9. Renal or hepatic disorders
10. Caretakers not willing to participate in the study

Discontinuation Criteria:

1. Any other acute illness.
2. Parents not willing to continue.
3. Any adverse effect of drug during trial.

Grouping of Patients: Cases registered for the study and satisfying inclusion criteria were divided into two groups. The subjects were enrolled by appropriate randomization technique.

Group A: Nutritional Rehabilitation: Dietary counselling and nutritional rehabilitation was done so that the child took recommended daily allowances as suggested by age specific Indian council of medical research (ICMR) guidelines.

Group B: Nutritional Rehabilitation Along with Trial Drug (*ChaturjatadiSambharaka*): Patients in this group received *"ChaturjatadiSambharaka*" along with dietary counselling and nutritional rehabilitation.

TABLE 1: TRIAL DRUG, *CHATURJATA DISAMBHARAKA* (*GADANIGRAHA, BALROGADHIKARA*, 11/77-79

S. no.	Ingredient	Scientific Name	Parts used	Proportion
1	Dalchini	*Cinnamomum zeylanicum*	Twak, Taila, Leaves	1 part
2	Ela	*Elettaria cardamomum*	Seeds	1 part
3	Tejpatra	*Cinnamomum tamala*	Leaves	1 part
4	Nagkeshara	*Mesua ferrea*	Punkeshar	1 part
5	Talisapatra	*Abies webbiana*	Leaves	1 part
6	Kushtha	*Saussurealappa*	Root	1 part
7	Shunthi	*Zingiber officinale*	Rhizome	1 part
8	Maricha	*Piper nigrum*	Fruit	1 part
9	Pippali	*Piper longum*	Fruit, Root	1 part
10	Chavya	*Piper retrofractum*	Root, Fruit	1 part
11	Pippalimula	*Piper longum*	Root	1 part
12	Tavaksheera	*Bambusaarundinacea*	Root, Leaves, Fruit	1 part
13	Shveta Jeera	*Cuminum cyminum*	Seeds	1 part
14	Ashwagandha	*Withaniasomnifera*	Root	1 part
15	Khanda (sharkara)	-	-	28 part
16	Ghrita	Cow-ghee		28 part

Method of Drug Preparation: The compound was in form of *Avaleha* in order to enhance its palatability and easy administration in children. The trial drug was prepared in the pharmacy of National institute of Ayurveda, Jaipur.

Dose: 180-200mg/kg/day. The proposed trial drug, was prescribed in doses according to body weight of children for 08 weeks and follow up was done fortnightly. Doses were calculated according to Clarks Formula.

Duration: 08 weeks

Assessment Criteria: The result of the clinical study was assessed based on the observations of clinical features, anthropometric parameters and laboratory findings. Following parameters was adopted for assessing the patients before and after treatment:

- Clinical (Clinical features and Anthropometric parameters).
- Laboratory Parameters.

Clinical Assessment: It was done on the basis of clinical features of *Balshosha* anthropometric parameters.

Clinical Features: Assessment of clinical features (*Arochaka, Jwara, Pratishyaya, Kasa, Mukha Snigdhata, Mukha Shwetata, Netra Snigdhata, Netra Shwetata, Shwasa, Shothaa* and *Kesha Shushkata*) depending on the severity was done on four-point scale

Nil - G0, Mild - G1, Moderate - G2, Severe - G3

Anthropometry Parameters:

1. Weight for age criteria.
2. Body mass index (B.M.I.).
3. Mid arm circumference (M.A.C) in cm.
4. Skin fold thickness (S.F.T.) in cm or mm
5. Height in cm.
6. Chest circumference in cm.

Laboratory Parameters:

1. Hb%, DLC, TLC, ESR.
2. Total protein level.
3. Serum albumin.
4. A: G ratio.

Adverse Effect Evaluation Criteria: To rule out the possible adverse effect of studied drug clinical criteria was adopted and was documented in AEEF (Adverse Effect Evaluation Format) during the course of the study.

Follow-Up: All patients were followed on an interval of 2 weeks i.e. on day 14, day 28, 42 and day 56 after recruitment. A window period of ±3 days was given to allow for holidays and weekends.

Proforma: The protocol required information was collected on each patient using printed proforma (Informed consent/ Case record form). Updated case record forms was kept safe for data analysis.

Ethical Clearance: Ethical clearance of the present trial obtained from Institutional Ethics Committee, after deliberation on 8th & 9th May Reference No. IEC/ACA/2019/1-19, National Institute of Ayurveda, Jaipur.

CTRI Registration: Prior to the start the clinical trial was applied for registration in CTRI with reference number REF/2020/07/035175 and CTRI with Registration No. CTRI/2020/09/53338.

Statistical Analysis: Group comparisons for continuously distributed data were made using independent sample‘t’ test when comparing two groups. If data were found to be non-normally distributed, appropriate non-parametric tests in the form of Wilcoxon Test were used. Chi-squared test was used for group comparisons for categorical data. In case the expected frequency in the contingency tables was found to be <5 for >25% of the cells, Fisher’s exact test was used. Repeated measures were analyzed using Paired t-test/Wilcoxon Signed Rank Test.

RESULTS:

TABLE 2: SUMMARY OF BASIC DETAILS

Basic Details	Mean ± SD || Median (IQR) || Min-Max || Frequency (%)
Group	
A	50 (50.0%)
B	50 (50.0%)

Age (Years)	6.21 ± 2.72 || 6.00 (4.00-8.00) || 1.00 - 10.00
Gender	
Male	55 (55.0%)
Female	45 (45.0%)
Father Age (Years)	33.48 ± 5.17 || 33.50 (30.00-36.00) || 25.00 - 45.00
Mother Age (Years)	28.24 ± 4.78 || 28.00 (25.00-31.25) || 19.00 - 40.00
Religion	
Hindu	86 (86.0%)
Muslim	14 (14.0%)
Weight (Kg)	15.86 ± 5.48 || 15.50 (12.00-19.50) || 7.00 - 26.00
Height (cm)	108.45 ± 17.21 || 110.00 (98.00-121.12) || 68.00 - 141.00
BMI (Kg/m2)	13.07 ± 1.40 || 12.95 (12.15-14.03) || 10.40 - 16.30
SFT (mm)	4.84 ± 1.13 || 4.20 (4.10-5.12) || 4.00 - 7.50
MUAC (cm)	12.74 ± 0.91 || 12.50 (12.00-13.50) || 11.00 - 14.80
Chest Circumference (cm)	57.34 ± 5.18 || 57.50 (53.88-61.00) || 48.00 - 66.00
Socio-Economic Status	
Upper Middle	3 (3.0%)
Middle	22 (22.0%)
Lower Middle	75 (75.0%)
Family Type	
Nuclear	61 (61.0%)
Joint	39 (39.0%)
Residence	
Urban	88 (88.0%)
Rural	12 (12.0%)
Hygeine	
Poor	44 (44.0%)
Average	26 (26.0%)
Normal	23 (23.0%)
Good	7 (7.0%)
Diet	
Vegetarian	71 (71.0%)
Mixed	29 (29.0%)
Mode Of Delivery	
SVD	84 (84.0%)
LSCS	16 (16.0%)
Fetal Maturity	
Full Term	88 (88.0%)
Preterm	12 (12.0%)
Fetal Weight	
WNL	72 (72.0%)
LBW	23 (23.0%)
VLBW	3 (3.0%)
Overweight	2 (2.0%)
Birth Weight (Kg)	2.55 ± 0.40 || 2.60 (2.30-2.80) || 1.20 - 4.00
Mode Of Feeding	
Breastfeeding	82 (82.0%)
Breastfeeding + Top Feeding	18 (18.0%)
Weaning	
Due Time	68 (68.0%)
Early	16 (16.0%)
Late	16 (16.0%)
Immunization	
Complete	79 (79.0%)
Not Complete	14 (14.0%)
Unimmunized	3 (3.0%)
Unknown	4 (4.0%)
Spacing Between Pregnancies (Years)	2.81 ± 0.76 || 3.00 (2.00-3.00) || 1.00 - 4.00
Appetite	

Poor	62 (62.0%)
Average	18 (18.0%)
Good	20 (20.0%)
Agni	
Mandagni	77 (77.0%)
Vishmagni	15 (15.0%)
Teekshanagni	8 (8.0%)
Koshtha	
Krura	50 (50.0%)
Madhayam	27 (27.0%)
Mridu	23 (23.0%)
Satva	
Avar	76 (76.0%)
Madhyama	24 (24.0%)
Prakriti	
VK	68 (68.0%)
VP	25 (25.0%)
PK	7 (7.0%)

TABLE 3: COMPARISON OF THE TWO GROUPS IN TERMS OF CHANGE IN WEIGHT (KG) OVER TIME (N =50)

Weight (Kg)	Group		P value for comparison of the two groups at each of the timepoints (Wilcoxon-Mann-Whitney Test)
	A	B	
	Mean (SD)	Mean (SD)	
Before Treatment	16.17 (5.85)	15.50 (5.12)	0.532
After Treatment	16.59 (5.84)	18.15 (5.12)	0.183
P Value for change in Weight (Kg) over time within each group (Wilcoxon Test)	<0.001	<0.001	
Overall P Value for comparison of change in Weight (Kg) over time between the two groups (Generalized Estimating Equations)	<0.001		

TABLE 4: COMPARISON OF THE TWO GROUPS IN TERMS OF CHANGE IN HEIGHT (CM) OVER TIME (N = 50)

Height (cm)	Group		P value for comparison of the two groups at each of the timepoints (Wilcoxon-Mann-Whitney Test)
	A	B	
	Mean (SD)	Mean (SD)	
Before Treatment	106.52 (16.80)	110.61 (17.41)	0.259
After Treatment	107.52 (16.71)	113.08 (17.42)	0.136
P Value for change in Height (cm) over time within each group (Wilcoxon Test)	<0.001	<0.001	
Overall P Value for comparison of change in Height (cm) over time between the two groups (Generalized Estimating Equations)	<0.001		

TABLE 5: COMPARISON OF THE TWO GROUPS IN TERMS OF CHANGE IN BMI (KG/M2) OVER TIME (N = 50)

BMI (Kg/m2)	Group		P value for comparison of the two groups at each of the time points (Wilcoxon-Mann-Whitney Test)
	A	B	
	Mean (SD)	Mean (SD)	
Before Treatment	13.69 (1.27)	12.38 (1.27)	<0.001
After Treatment	13.83 (1.18)	14.08 (1.59)	0.850
P Value for change in BMI (Kg/m2) over time within each group (Wilcoxon Test)	0.021	<0.001	
Overall P Value for comparison of change in BMI (Kg/m2) over time between the two groups (Generalized Estimating Equations)	<0.001		

TABLE 6: COMPARISON OF THE TWO GROUPS IN TERMS OF CHANGE IN SFT (MM) OVER TIME (N = 50)

SFT (mm)	Group		P value for comparison of the two groups at each of the timepoints (Wilcoxon-Mann-Whitney Test)
	A	B	
	Mean (SD)	Mean (SD)	

Before Treatment	4.77 (1.13)	4.90 (1.14)	0.717
After Treatment	4.86 (1.12)	5.00 (1.20)	0.716
P Value for change in SFT (mm) over time within each group (Wilcoxon Test)	<0.001	<0.001	
Overall P Value for comparison of change in SFT (mm) over time between the two groups (Generalized Estimating Equations)	0.471		

TABLE 7: COMPARISON OF THE TWO GROUPS IN TERMS OF CHANGE IN MUAC (CM) OVER TIME (N = 50)

MUAC (cm)	Group		P value for comparison of the two groups at each of the timepoints (Wilcoxon-Mann-Whitney Test)
	A	B	
	Mean (SD)	Mean (SD)	
Before Treatment	13.34 (0.87)	12.14 (0.43)	<0.001
After Treatment	13.80 (0.83)	13.74 (0.41)	0.445
P Value for change in MUAC (cm) over time within each group (Wilcoxon Test)	<0.001	<0.001	
Overall P Value for comparison of change in MUAC (cm) over time between the two groups (Generalized Estimating Equations)	<0.001		

TABLE 8: COMPARISON OF THE TWO GROUPS IN TERMS OF CHANGE IN CHEST CIRCUMFERENCE (CM) OVER TIME (N = 50)

Chest Circumference (cm)	Group		P value for comparison of the two groups at each of the timepoints (Wilcoxon-Mann-Whitney Test)
	A	B	
	Mean (SD)	Mean (SD)	
Before Treatment	57.23 (5.23)	57.44 (5.18)	0.751
After Treatment	57.86 (5.29)	58.65 (5.02)	0.454
P Value for change in Chest Circumference (cm) over time within each group (Wilcoxon Test)	<0.001	<0.001	
Overall P Value for comparison of change in Chest Circumference (cm) over time between the two groups (Generalized Estimating Equations)	<0.001		

Changes in Clinical Features: Figure Number is to be written in place of Chart Number:

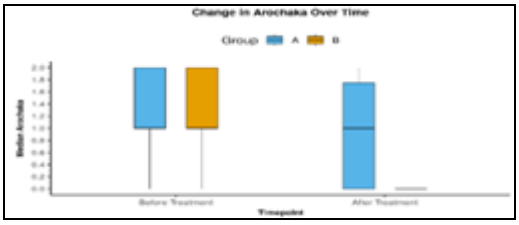

FIG. 1:

FIG. 2:

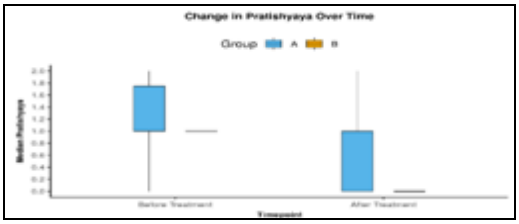

FIG. 3:

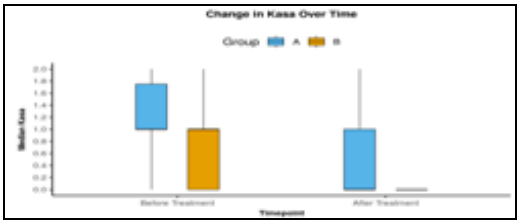

FIG. 4:

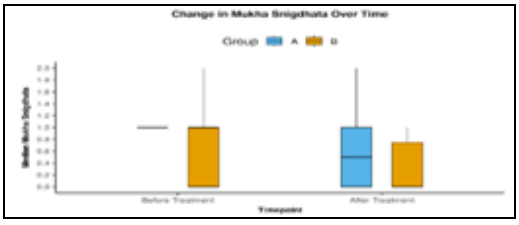

FIG. 5:

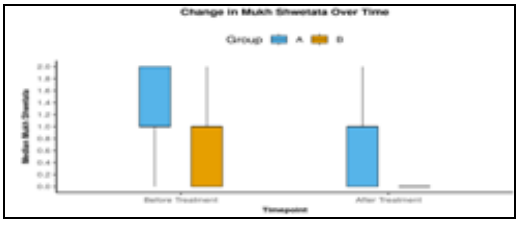

FIG. 6:

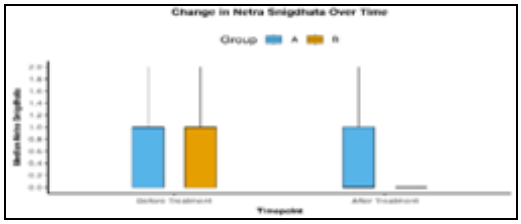

FIG. 7:

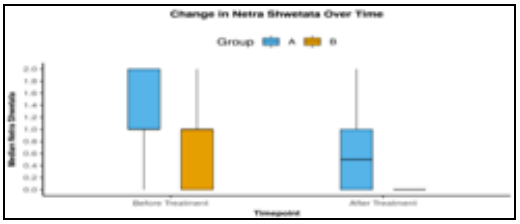

FIG. 8:

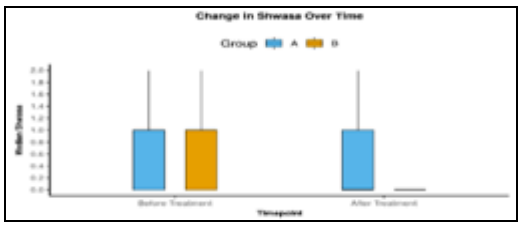

FIG. 9:

FIG. 10:

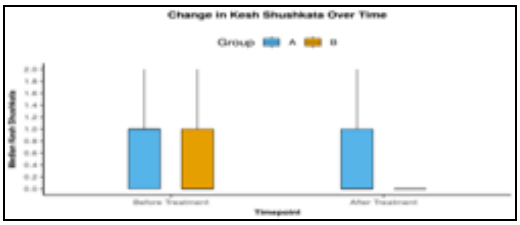

FIG. 11:

TABLE 9: COMPARISON OF THE TWO GROUPS IN TERMS OF CHANGE IN HEMOGLOBIN (G/DL) OVER TIME (N = 50)

Hemoglobin (g/dL)	Group		P value for comparison of the two groups at each of the timepoints (t-Test)
	A	B	
	Mean (SD)	Mean (SD)	
Before Treatment	10.79 (1.41)	11.01 (1.12)	0.390
After Treatment	11.58 (1.31)	13.08 (0.93)	<0.001
P Value for change in Hemoglobin (g/dL) over time within each group (Paired t-test)	<0.001	<0.001	
Overall P Value for comparison of change in Hemoglobin (g/dL) over time between the two groups (Generalized Estimating Equations)	<0.001		

TABLE 10: COMPARISON OF THE TWO GROUPS IN TERMS OF CHANGE IN ESR OVER TIME (N = 50)

ESR	Group		P value for comparison of the two groups at each of the timepoints (Wilcoxon-Mann-Whitney Test)
	A	B	
	Mean (SD)	Mean (SD)	
Before Treatment	15.08 (4.47)	14.12 (4.71)	0.236
After Treatment	14.10 (3.99)	10.17 (2.77)	<0.001
P Value for change in ESR over time within each group (Wilcoxon Test)	<0.001	<0.001	
Overall P Value for comparison of change in ESR over time between the two groups (Generalized Estimating Equations)	<0.001		

TABLE 11: COMPARISON OF THE TWO GROUPS IN TERMS OF CHANGE IN TOTAL PROTEINS (G/DL) OVER TIME (N = 50)

Total Proteins (g/dL)	Group		P value for comparison of the two groups at each of the timepoints (Wilcoxon-Mann-Whitney Test)
	A	B	
	Mean (SD)	Mean (SD)	
Before Treatment	5.48 (0.58)	5.61 (0.43)	0.513
After Treatment	6.07 (0.63)	6.87 (0.30)	<0.001

P Value for change in Total Proteins (g/dL) over time within each group (Wilcoxon Test)	<0.001	<0.001
Overall P Value for comparison of change in Total Proteins (g/dL) over time between the two groups (Generalized Estimating Equations)	<0.001	

TABLE 12: COMPARISON OF THE TWO GROUPS IN TERMS OF CHANGE IN SERUM ALBUMIN (G/DL) OVER TIME (N = 50)

Serum Albumin (g/dL)	Group		P value for comparison of the two groups at each of the timepoints (Wilcoxon-Mann-Whitney Test)
	A	B	
	Mean (SD)	Mean (SD)	
Before Treatment	3.94 (0.50)	4.37 (0.23)	<0.001
After Treatment	4.41 (0.47)	4.58 (0.21)	0.213
P Value for change in Serum Albumin (g/dL) over time within each group (Wilcoxon Test)	<0.001	<0.001	
Overall P Value for comparison of change in Serum Albumin (g/dL) over time between the two groups (Generalized Estimating Equations)	<0.001		

TABLE 13: COMPARISON OF THE TWO GROUPS IN TERMS OF CHANGE IN A: G RATIO OVER TIME (N = 50)

A: G Ratio	Group		P value for comparison of the two groups at each of the timepoints (Wilcoxon-Mann-Whitney Test)
	A	B	
	Mean (SD)	Mean (SD)	
Before Treatment	3.22 (1.94)	3.95 (1.34)	0.003
After Treatment	3.51 (2.49)	2.07 (0.37)	<0.001
P Value for change in A:G Ratio over time within each group (Wilcoxon Test)	0.303	<0.001	
Overall P Value for comparison of change in A:G Ratio over time between the two groups (Generalized Estimating Equations)	<0.001		

DISCUSSION: In present study, patients were treated in two individual Groups. In Group A Nutritional Rehabilitation and in Group B Nutritional Rehabilitation along withTrial drug (*Chaturjatadi Sambharaka*) were administered. Both the groups received standard diet according to their grade of malnutrition and body weight. The results were observed and evaluated for anthropometric variables, clinical symptoms and laboratory parameters at the end of entire course.

The clinical efficacy of the drug was analyzed statistically on all parameters mentioned in the Assessment criteria. A scoring structure was employed to evaluate the effectiveness of therapy. Scoring of chief clinical features was done before and after treatment. Thus, Group comparisons for continuously distributed data were made using independent sample‘t’ test when comparing two groups. If data were found to be non-normally distributed, appropriate non-parametric tests in the form of Wilcoxon Test were used. Chi-squared test was used for group comparisons for categorical data. In case the expected frequency in the contingency tables was found to be <5 for >25% of the cells, Fisher’s exact test was used. Repeated measures were analyzed using Paired t-test/Wilcoxon Signed Rank Test. Statistical significance was kept at $p < 0.05$. More specific quantification of the percentage improvement in each feature the formula BT-AT/BT x 100 was applied. All the parameters adopted i.e. anthropometric variables, clinical features and laboratory values were statistically analyzed and after that results of every parameter are being discussed hereunder.

Effect on Anthropometric Variables:

Weight: The mean Weight (Kg) was 15.86 ± 5.48. The Weight (Kg) ranged from 7 – 26. In Group: A, the mean Weight (Kg) increased from a minimum of 16.17 at the Before Treatment time point to a maximum of 16.59 at the After Treatment time point. This change was statistically significant (Wilcoxon Test: V = 0.0, p = <0.001). In Group: B, the mean Weight (Kg) increased from a minimum of 15.50 at the Before Treatment time point to a maximum of 18.15 at the After Treatment time

point. This change was statistically significant (Wilcoxon Test: V = 0.0, p = <0.001). There was a significant difference in the trend of Weight (Kg) over time between the two groups (p = <0.001).

Height: The mean Height (cm) was 108.45± 17.21. The Height (cm) ranged from 68 – 141. In Group: A, the mean Height (cm) increased from a minimum of 106.52 at the Before Treatment timepoint to a maximum of 107.52 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 0.0, p = <0.001). In Group: B, the mean Height (cm) increased from a minimum of 110.61 at the Before Treatment timepoint to a maximum of 113.08 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 0.0, p = <0.001). There was a significant difference in the trend of Height (cm) over time between the two groups (p = <0.001).

BMI: The mean BMI (Kg/m2) was 13.07± 1.40. The BMI (Kg/m2) ranged from 10.4 - 16.3. In Group: A, the mean BMI (Kg/m2) increased from a minimum of 13.69 at the Before Treatment timepoint to a maximum of 13.83 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 381.0, p = 0.021). In Group: B, the mean BMI (Kg/m2) increased from a minimum of 12.38 at the Before Treatment timepoint to a maximum of 14.08 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 0.0, p = <0.001). There was a significant difference in the trend of BMI (Kg/m2) over time between the two groups (p = <0.001)**.**

SFT: The mean SFT (mm) was 4.84 ± 1.13. The SFT (mm) ranged from 4 - 7.5. In Group: A, the mean SFT (mm) increased from a minimum of 4.77 at the Before Treatment timepoint to a maximum of 4.86 at the After Treatment timepoint.

This change was statistically significant (Wilcoxon Test: V = 0.0, p = <0.001). In Group: B, the mean SFT (mm) increased from a minimum of 4.90 at the Before Treatment timepoint to a maximum of 5.00 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 0.0, p = <0.001). There was no significant difference in the trend of SFT (mm) over time between the two groups (p = 0.471).

MUAC: The mean MUAC (cm) was 12.74 ± 0.91. The MUAC (cm) ranged from 11 - 14.8. In Group: A, the mean MUAC (cm) increased from a minimum of 13.34 at the Before Treatment timepoint to a maximum of 13.80 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 0.0, p = <0.001). In Group: B, the mean MUAC (cm) increased from a minimum of 12.14 at the Before Treatment timepoint to a maximum of 13.74 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 0.0, p = <0.001). There was a significant difference in the trend of MUAC (cm) over time between the two groups (p = <0.001).

Chest Circumference: The mean Chest Circumference (cm) was 57.34 ± 5.18. The Chest Circumference (cm) ranged from 48 – 66.In Group: A, the mean Chest Circumference (cm) increased from a minimum of 57.23 at the Before Treatment timepoint to a maximum of 57.86 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 0.0, p = <0.001). In Group: B, the mean Chest Circumference (cm) increased from a minimum of 57.44 at the Before Treatment timepoint to a maximum of 58.65 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 0.0, p = <0.001). There was a significant difference in the trend of Chest Circumference (cm) over time between the two groups (p = <0.001).

After 56 days of intervention, it was observed that, significant improvement was observed in all anthropometric parameters. This could be attributed to *Snigdha, Pichchhila, Guru, Brimhana* and *Rasayana* properties of the drug which helps to nourish the *Rasa, Mamsa*, *Medodhatu*.

Thus, on overall evaluation in group B patients who were on trial drug had a better outcome in comparison to group A who were only on nutritional rehabilitation. This may be because drug compound acts on the pathogenesis of *Balshosha*, by breaking it and by balancing of *Agni*. Drug promotes appetite; enhance bioavailability of nutrients and acts as anabolic agent, thus increasing

quantity of diet to be taken and best utilisation of it to form body tissues. Thus, assimilation of nutrients is better due balanced *Agni* and there is rapid recovery with formation of *Prashasta dhatus*(best tissue quality) in group B.

On individual analysis of groups; both the groups show significant results in anthropometric parameters but on intergroup analysis group B showed significant advantage over Group A. Results point out that standard diet has good effect on anthropometric parameters but with administration of drug, a very prompt and superior outcome can be achieved.

Effect on Clinical Features of *Balshosha:*

***Arochaka*:** In Group: A, the mean *Arochaka* decreased from a maximum of 1.28 at the Before Treatment timepoint to a minimum of 0.94 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 153.0, p = <0.001). In Group: B, the mean *Arochaka* decreased from a maximum of 1.36 at the Before Treatment timepoint to a minimum of 0.14 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 1176.0, p = <0.001). There was a significant difference in the trend of *Arochaka* over time between the two groups (p = <0.001).

***Jwara*:** In Group: A, the mean *Jwara* decreased from a maximum of 1.04 at the Before Treatment timepoint to a minimum of 0.58 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 231.0, p = <0.001). In Group: B, the mean *Jwara* decreased from a maximum of 1.04 at the Before Treatment timepoint to a minimum of 0.14 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 861.0, p = <0.001). There was a significant difference in the trend of *Jwara* over time between the two groups (p = <0.001).

***Pratishyaya*:** In Group: A, the mean *Pratishyaya* decreased from a maximum of 1.06 at the Before Treatment timepoint to a minimum of 0.64 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 231.0, p = <0.001). In Group: B, the mean *Pratishyaya* decreased from a maximum of 1.02 at the Before Treatment timepoint to a minimum of 0.14 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 861.0, p = <0.001). There was a significant difference in the trend of *Pratishyaya* over time between the two groups (p = <0.001).

***Kasa*:** In Group: A, the mean *Kasa* decreased from a maximum of 1.02 at the Before Treatment timepoint to a minimum of 0.58 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 231.0, p = <0.001). In Group: B, the mean *Kasa* decreased from a maximum of 0.88 at the Before Treatment timepoint to a minimum of 0.18 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 595.0, p = <0.001). There was a significant difference in the trend of *Kasa* over time between the two groups (p = 0.012).

***Shwasa*:** In Group: A, the mean *Shwasa* decreased from a maximum of 0.90 at the Before Treatment timepoint to a minimum of 0.44 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 276.0, p = <0.001). In Group: B, the mean *Shwasa* decreased from a maximum of 0.76 at the Before Treatment timepoint to a minimum of 0.06 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 561.0, p = <0.001). There was a significant difference in the trend of *Shwasa* over time between the two groups (p = 0.021)**.**

***Mukha Snigdhata*:** In Group: A, the mean *Mukha Snigdhata* decreased from a maximum of 1.06 at the Before Treatment timepoint to a minimum of 0.64 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 231.0, p = <0.001). In Group: B, the mean *MukhaSnigdhata* decreased from a maximum of 0.86 at the Before Treatment timepoint to a minimum of 0.26 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 465.0, p = <0.001). There was no significant difference in the trend of *MukhaSnigdhata* over time between the two groups (p = 0.067).

***Netra Snigdhata*:** In Group: A, the mean *NetraSnigdhata* decreased from a maximum of 0.94 at the Before Treatment timepoint to a minimum of 0.52 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 231.0, p = <0.001). In Group: B, the mean *NetraSnigdhata* decreased from a maximum of 0.72 at the Before Treatment timepoint to a minimum of 0.22 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 300.0, p = <0.001). There was no significant difference in the trend of *NetraSnigdhata* over time between the two groups (p = 0.439).

***MukhaShwetata*:** In Group: A, the mean *MukhaShwetata* decreased from a maximum of 1.12 at the Before Treatment timepoint to a minimum of 0.74 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 190.0, p = <0.001). In Group: B, the mean *MukhaShwetata* decreased from a maximum of 0.82 at the Before Treatment timepoint to a minimum of 0.18 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 496.0, p = <0.001). There was a significant difference in the trend of *MukhaShwetata* over time between the two groups (p = 0.010).

***Netra Shwetata*:** In Group: A, the mean *NetraShwetata* decreased from a maximum of 1.16 at the Before Treatment timepoint to a minimum of 0.72 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 253.0, p = <0.001). In Group: B, the mean *NetraShwetata* decreased from a maximum of 0.92 at the Before Treatment timepoint to a minimum of 0.20 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 595.0, p = <0.001). There was a significant difference in the trend of *NetraShwetata* over time between the two groups (p = 0.006).

***Shotha*:** In Group: A, the mean *Shotha* decreased from a maximum of 0.66 at the Before Treatment timepoint to a minimum of 0.38 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 105.0, p = <0.001). In Group: B, the mean *Shotha* decreased from a maximum of 0.42 at the Before Treatment timepoint to a minimum of 0.10 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 136.0, p = <0.001). There was no significant difference in the trend of *Shotha* over time between the two groups (p = 0.662).

***Kesh Shushkata*:** In Group: A, the mean *KeshShushkata* decreased from a maximum of 0.64 at the Before Treatment timepoint to a minimum of 0.34 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 120.0, p = <0.001). In Group: B, the mean *KeshShushkata* decreased from a maximum of 0.48 at the Before Treatment timepoint to a minimum of 0.12 at the After Treatment timepoint, This change was statistically significant (Wilcoxon Test: V = 171.0, p = <0.001). There was no significant difference in the trend of *KeshShushkata* over time between the two groups (p = 0.523).

Effect on Laboratory Parameters:

Hemoglobin: In Group: A, the mean Hemoglobin (g/dL) increased from a minimum of 10.79 at the Before Treatment timepoint to a maximum of 11.58 at the After Treatment timepoint. This change was statistically significant (Paired t-test: t = -11.2, p = <0.001). In Group: B, the mean Hemoglobin (g/dL) increased from a minimum of 11.01 at the Before Treatment timepoint to a maximum of 13.08 at the After Treatment timepoint. This change was statistically significant (Paired t-test: t = -21.7, p = <0.001). There was a significant difference in the trend of Hemoglobin (g/dL) over time between the two groups (p = <0.001).

ESR: In Group: A, the mean ESR decreased from a maximum of 15.08 at the Before Treatment timepoint to a minimum of 14.10 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 903.0, p = <0.001). In Group: B, the mean ESR decreased from a maximum of 14.12 at the Before Treatment timepoint to a minimum of 10.17 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 1275.0, p = <0.001). There was a significant difference in the trend of ESR over time between the two groups (p = <0.001).

Total Serum Protein: In Group: A, the mean Total Serum Protein (g/dL) increased from a minimum of 5.48 at the Before Treatment timepoint to a maximum of 6.07 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 0.0, p = <0.001). In Group: B, the mean Total Proteins (g/dL) increased from a minimum of 5.61 at the Before Treatment timepoint to a maximum of 6.87 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 0.0, p = <0.001). There was a significant difference in the trend of Total Serum Protein (g/dL) over time between the two groups (p = <0.001).

Serum Albumin: In Group: A, the mean Serum Albumin (g/dL) increased from a minimum of 3.94 at the Before Treatment timepoint to a maximum of 4.41 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 0.0, p = <0.001). In Group: B, the mean Serum Albumin (g/dL) increased from a minimum of 4.37 at the Before Treatment timepoint to a maximum of 4.58 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 0.0, p = <0.001). There was a significant difference in the trend of Serum Albumin (g/dL) over time between the two groups (p = <0.001).

A: G Ratio: In Group: A, the mean A:G Ratio increased from a minimum of 3.22 at the Before Treatment timepoint to a maximum of 3.51 at the After Treatment timepoint. This change was not statistically significant (Wilcoxon Test: V = 508.5, p = 0.303). In Group: B, the mean A:G Ratio decreased from a maximum of 3.95 at the Before Treatment timepoint to a minimum of 2.07 at the After Treatment timepoint. This change was statistically significant (Wilcoxon Test: V = 1273.0, p = <0.001). There was a significant difference in the trend of A:G Ratio over time between the two groups (p = <0.001).On overall analysis of laboratory parameters trial drug treated group B has significant improvement in Hemoglobin level, Total Serum Protein and A:G ratio. Group A showed not significant effects in improvement in A: G ratio.

Probable Action of the Drug: *Chaturjatadi Sambharaka* [3] is a well-balanced preparation including the drugs *having Deepana, Pachana, Vatanulomana, Krimighna, Jwara, Aruchi, Kasa, Shwasa, Kandu, Chhardi-Hrilashanashana, Vishahara, Rasayana, Brumhana, Vrushya, Balya* [4] properties which are very much essential in a *Shosha* predominant disease. *Chaturjatadi Sambharaka* including the drugs *Dalchini, Ela, Tejpatra, Nagkeshara, Talishpatra, Kushtha, Shunthi, Maricha, Pippali, Chavya, Pippalimula, Tavaksheera, Shweta Jeera, Ashwagandha, Khanda (Sharkara)* and *Ghrita*.

The drug possesses mainly *katu, tikta* and *madhurarasa*, *madhuravipaka, sheeta* as well as *ushnavirya*. The properties of contents are balancing each other having *laghu* as well as *guru, snigdha* and *ruksha*, *tikshna* properties. They are mainly *Kapha-Vatashamaka* and have therapeutic properties like *Agnideepana, Amapachana, Balya, Brimhana, Rasayana, Dhatuvardhaka, Ojovardhaka*, and *Srotoshodhaka etc*.

Because of these properties, there is nourishment to the *dhatus* as well as it improves *shosha* (wasting of tissues) and increase body weight. Moreover, *Madhura rasa* is considered as *satmya* for children in consideration to their age. The other dominant *rasa* is *Katu rasa* which is formed by *Vayu* and *Agni mahabhuta* thereby it controls *Agni,* also increase the absorption of food, increases interest in food, open blocked channels (*srotoshodhaka*), *Kledanashaka*, and is *Kaphashamaka*. Thus by these properties it breaks the pathogenesis of *Agnimandya janya srotorodha* which is root cause of *Balshosha*. Whole metabolism in our body is accelerated by *Katu rasa* that helps in absorption of micro as well macronutrients as per requirement in the body and thus decline nutrient deficiencies. The *Tikata rasa* is *Deepana-Pachana, Krimighna, Arochakaghna, Srotoshodhaka* and digest the *Ama* formed in the disease process. *Laghuguna* is called *Pathya, Kaphaghna*, *Lekhana* and is easily digestible due to which the drug get easily absorbed. By these properties it relieves the obstruction of *Rasavahasrotasa* by *Kapha* and is suitable to digest by disarranged *Agni* in *Balshosha* patients. The *Laghu-Rukshaguna* also increase the diminished *Agni* and helps to digest the *Pathyaahara*. The *Snigdhaguna* alleviates *Rukshata* and *Kharata* of *dhatus* by its *Snehana* and *Mridukarana* properties.

It also promotes the strength (*Bala*) in patients. The other properties of the drug include *Ruksha* which by its *Stambhana* action provide stability to *Asthira dhatus*. The *Guru guna*present in drug by its *Tarpana* and *Brimhana* actions increases the mass of body tissues. *Madhura Vipaka*is considered *Sarvadhatuposhaka, Balya* and *Brihmana.* The *SheetaVirya* is favorable in childhood by its *Mridu, Balya, Brimhana* and *Rasayana* action on *dhatus. UsnaVirya* alleviates *Kapha dosha* & *Ama*.

The pharmacological actions which are useful in malnutrition are digestive, bioavailability enhancer, hepto-protective, immunomodulator, antioxidant, antimicrobial, antiviral, antidiarrheal, antibacterial and growth promoting etc. *Twak* (*Cinnamomum zeylanicum*) has antimicrobial property [5]. *Ela* (*Elettaria cardamomum*) has immunomodulatory [6] and antioxidant effect [7]. *Tejapatra* (*Cinnamomum tamala*) has antibacterial effect [8]. *Tavaksheera* (*Bambusaarundinacea)* has Pancreas protective and hepatoprotective effect[9]. *Kushtha* (*Saussurealappa*) has anticancerous effect [10]. *Nagkeshara* (*Mesuaferrea)* has antioxidant effect [11]. *Shunthi* (*Zingiber officinale*) has anti-inflammatory, anti-tumour and antioxidant activities [12]. *Maricha* (*Piper nigrum)* has antimicrobial, antioxidant, anti inflammatory and neuroprotective effect [13]. *Pippali* (*Piperlongum*) has immunomodulatory activity [14] and bioavailability enhancer [15] *Chavya* (*Piper retrofractum*) has gastroprotective and cholesterol-lowering properties [16]. *ShvetaJeeraka* (*Cuminum cyminum*) has anti inflammatory, antioxidant and immunological activity [17]. *Ashwagandha* (*Withania somnifera*) has muscle mass promotive activity, improvement in the physical performance and strength [18]. *Sharkara* (*Saccharum officinarum)* has antioxidants effect[19]. Cow ghee has *Agnideepana, Anubhishyandi, Ayushya, Balya, Chakshushya, Deepana, Hridya, Kantiprada, Medhya, Ojovardhaka, Rasayana [20],* digestive, antioxidants, energetic, anti toxic, *medhyarasayana* and nourishing Property [21].

CONCLUSION: In the present randomized clinical trial, both groups, showed statistically significant (P<0.001) improvement on anthropometric parameters- Weight, Height, BMI, MUAC, SFT, and Chest circumference. However, on Intergroup comparison, group B (trial group) showed statistically significant advantage over group A (p<0.001). The trial drug (Group B) was also effective in improving clinical features of *Balshosha*/PEM as reflected in statistical result: significant (p< 0.001) in *Arochaka, Jwara, Pratishyaya, Kasa, Mukha Snigdhata, Mukha Shwetata, Netra Snigdhata, Netra Shwetata, Shwasa, Shotha* and *Kesh Shushkata.*

The trial drug (Group B) showed significant improvement on laboratory investigations in Hemoglobin level, Total Serum Protein and A:G ratio (p<0.001). The overall change over time was compared in the two groups A and B, there was a significant difference on Anthropometric Parameters- Weight, Height, BMI, MUAC and Chest Circumference (p <0.001) and not significant difference on SFT. The overall change over time was compared in the two groups A and B, there was a significant difference in clinical features of *Balshosha*/PEM *-Arochaka, Jwara, Pratishyaya, Kasa, MukhaShwetata, Netra Shwetata, and Shwasa*(p <0.001) and not significant difference in *MukhaSnigdhata,Netra Snigdhata, Shotha* and *Kesh Shushkata.*

The overall change over time was compared in the two groups A and B, there was a significant difference on laboratory investigations in Hemoglobin, TLC, Neutrophils, Lymphocytes, Monocyte, ESR , Total Proteins, Serum Albumin, A:G Ratio (p <0.001) and not significant difference in Basophil and Eosinophils. The trial drug (Group B) was effective in the management of PEM/*Balshosha* due to its therapeutic and nutritional properties: *Deepana, Pachana, Balya, Brimhana,and Rasayana.* No any adverse effects of the drug therapy were observed during the present study. The present study was done with a small sample of patients. The results obtained are just a preview of information for future researchers to study involving large sample size. It is expected that the further study on this project could be beneficial for the children suffering from *Balashosha*w.s.r. to PEM.

ACKNOWLEDGEMENT: The authors are thankful to the institute for providing necessary facilities.

CONFLICTS OF INTEREST: The authors declare that there is no conflict of interest.

REFERENCES:

1. https://www.who.int/news-room/questions-and-answers/item/malnutrition Retrieved on 12-06-2021
2. https://www.who.int/data/nutrition/nlis/info/infant-and-young-child-feeding Retrieved on 12-06-2021.
3. Gadanigraha, of Sodhal with hindi commentary by Sri Indradev Tripathi, Chowkhamba Sanskrit Series Office, Varanasi; Balrogadhikara 11/77-79
4. Bhavprakash Nighantu of Sri Bhavmisra, Commentary by Prof. K.C. Chunekar; Edited by Dr.G. S. Pandey, Chaukhambha Bharati Academy; Varanasi Reprint Guduchyadi Varga 2013; 379.
5. Gupta C, Garg AP, Uniyal RC and Kumari A: Comparative analysis of the antimicrobial activity of cinnamon oil and cinnamon extract on some food-borne microbes. Afr J Microbiol Res 2008; 2: 247–251.
6. Majdalawieh AF and Carr RI: *In-vitro* investigation of the potential immunomodulatory and anti-cancer activities of black pepper (*Piper nigrum*) and cardamom (*Elettaria cardamomum*). J Med Food 2010; 13(2): 371-81.
7. Verma SK, Jain V and Katewa SS: Blood pressure lowering, fibrinolysis enhancing and antioxidant activities of cardamom (*Elettaria cardamomum*). Indian J Biochem Biophys 2009; 46(6): 503-6.
8. Rath S and Padhy RN: Monitoring *in-vitro* antibacterial efficacy of 26 Indian spices against multidrug resistant tract infecting bacteria. Integ Med Res 2014; 3(3): 133-41.
9. Ahmad D, Sharma M, Mukerjee A, Ramteke PW and Kumar V: Improved Glycemic control, pancreas protective and hepatoprotective effect by traditional poly-herbal formulation (ours tabasheer) in streptozocin induced diabetic rats. BMC Complement Altern Med 2013; 13-10. Doi 10.1186/1472-6882-13-10
10. Tian X Song, Cho HS, Park YM, Song B, YJ, Jang S & Kang SC: Anticancereffect of saussurealappa extract via dual control of apoptosis and autophagy in prostate cancer cells, Medicine 2017; 96(30): 7606.
11. Asif M, Shafaei A, Abdul Majid AS, Ezzat MO, Dahham SS, Ahmed MBK, Oon CE and Abdul Majid AMS: Mesuaferrea stem bark extract induces apoptosis and inhibits metastasis in human colorectal carcinoma hct 116 cells through modulation of multiple cell signaling pathways. Chin JNat Med 2017; 15(7): 505-514. Doi: 10.1016/s1875-5634(17)30076-6
12. Nagendra Chari KL, Manasa D, Srinivas P and Sowbhagya HB: Enzyme-assisted extraction of bioactive compounds from ginger (*Zingiber officinale* Roscoe). Food Chem 2013139: 509-514.
13. Takooree H, Aumeeruddy MZ, Rengasamy KRR, Venugopala KN, Jeewon R, Zengin G and Mahomoodally MF: A systematic review on black pepper (Piper nigrum L.): from folk uses to pharmacological applications. Crit Rev Food Sci Nutr 2019; 1-34.
14. Devan P, Bani S, Suri KA: Immunomodulation exhibited by piperinic acid of Piperlongum L; through suppression of proinflammatory cytokines. Int Immunopharmacol 2007; 7(7): 889-899.
15. Khajuria A, Thusu N and Zutshi U: Piperine modulates permeability characteristics of intestine by inducing alterations in membrane dynamics: influence on brush border membrane fluidity, ultrastructure and enzyme kinetics. Phytomedicine 2002; 9(3): 224-31.
16. Kim KJ: Piperidine alkaloids from *Piper retrofractum* Vahl. protect against high-fat diet induced obesity by regulating lipid metabolism and activating AMP-activated protein kinase 2011; 411(1): 219-25. doi: 10.1016/j.bbrc.2011.06.153.
17. Ali Esmail Al-Snafi: The Pharmacological activities of Cuminumcyminum- A review. IOSR Journal of Pharmacy 2016; 6(6): 46-65
18. Raut AA, Rege NN, Tadvi FM, Solanki PV, Kene KR, Shirolkar SG, Pandey SN and Vaidya AB: Exploratory study to evaluate tolerability, safety, and activity of Ashwagandha (*Withania somnifera*) in healthy volunteers. J Ayurveda Integr Med 2012; 3(3): 111-4.
19. Guan Y, Tang Q, Fu X, Yu S, Wu S and Chen M: Preparation of antioxidants from sugarcane molasses. Food Chem 2014; 152: 552-557.
20. API, Part-1 Vol-IV
21. Ankita Mahakalkar, Pranita Kashyap, Ram Bawankar and Bhushan Hatwar: The versatility of Cow Ghee – An Ayurveda Perspective. American Journal of Drug Delivery and Therapeutics 2014; 1(1): 028-034.

How to cite this article:
Meena V: A community based study to evaluate the efficacy of Chaturjatadi Sambharaka on the nutritional status of children with Balshosha W.S.R. to protein energy malnutrition. Int J Pharm Sci & Res 2023; 14(7): 3596-10. doi: 10.13040/IJPSR.0975-8232.14(7).3596-10.