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A RANDOMIZED PLACEBO CONTROLLED CLINICAL TRIAL TO EVALUATE THE EFFICACY OF VIDARIKANDADI CHURNA IN THE MANAGEMENT OF BALASHOSHA W.S.R TO UNDERWEIGHT CHILDREN

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ABSTRACT

Under nutrition and problems associated with complementary feeding are of great concern in the field of paediatrics. It has been estimated that in India, 65 percent i.e., nearly 80 million children under five years of age suffer from varying degrees of malnutrition. Mothers are expected to make a bridge of complementary feeding. This includes utilization of 'Supplementary Feeding Programmes'. The trial was proposed to study the efficacy of Vidarikandadi Churna during complementary feeding by using specific parameters for Balashosha w.s.r to underweight children. Children showed improvement in all aspects of such as height, weight and BMI. It was concluded that consumption of Vidarikandadi Churna along with Ghrita followed by sukhoshnaksheera is found effective in the management of Balashosha w.s.r underweight in children when compared to placebo.

KEYWORDS: Vidarikandadi Churna, Balashosha, underweight, nutritional supplement.

INTRODUCTION

The dimensions of health are always changing.[1] The concept of health envisages several spiritual, emotional, vocational and political dimensions.[2] Presently exploring medical requirements are most of the time incapable to fulfill this views.[3]

Infant and young child feeding is the subject of great concern in the field of nutrition since malnutrition in early childhood has serious, long-term consequences because it impedes motor, sensory, cognitive, social and emotional development. Malnourished children are less likely to perform well in school and more likely to grow into malnourished adults, at greater risk of disease and early death.[4] One in three of the world's malnourished children live in India.[5] Improper nutrition during weaning and post weaning period is the root cause of malnutrition in children[6], and also with some consequence associated with many disorders like constipation, diarrhea, colic and this age group has unstable agni[7] etc. This physical and mental turmoil along with the need for a highly nutritious diet points out the importance of an ideal weaning food.

MATERIALS AND METHODS

Preparation of Vidarikandadi Choorna: Vidarikandadi Churna will be prepared as per classical method in GMP certified SDM Pharmacy Kuthpady, Udupi.

Method: The ingredients were taken clean and dried properly. The individual drugs according to the parts mentioned are pulverized to get powder form. They were filtered in 80 number meshes to get uniform fine powder. Then all the drugs in powder form were mixed properly and packed into 150 grams air tight packets.

Selection of cases: Children will be selected from OPD and IPD of S.D.M. College of Ayurveda and Hospital, Udupi, as well as from Anganvadi in and around Udupi.

Inclusion criteria

1. The children of either sex between the age of 2-3 yrs.
2. Clinically stable child.
3. Weight of child less than expected as per the age.
4. The children with underweight having one or two symptoms of Balashosha as explained in Ayurvedic classics such as arochaka, mukhanetrashuklata (panduta).

Exclusion criteria

1. Children suffering from fever, cold and cough.

2. Children suffering from any systemic illness such as Tuberculosis, Juvenile Diabetes, Infectious diseases.
3. Severely malnourished children.
4. Endocrine disturbances like Hyperthyroidism.

Method of study

Study design: It was a randomized control trial (RCT). 40 infants were divided randomly into two groups, each consisting of 20 infants andstudy was conducted as per the schedule.

Table no. 1: Study design.

Group	Sample size	Intervention	Duration
A	20	VidarikandadiChurna with ghrita with sukhoshnaksheer as anupana along with food as being practiced at home.	30 days
B	20	Placebo with ushnodaka along with food as being practiced at home.	30 days

Review of formulation

Table no. 2: Vidarikandadi Churna Ingredients.

Drug name	Botanical name	Part used	Quantity
Vidarikanda	Pueraria tuberose	Tuber	1 part
Yava	Hordeumvulgarae	Seed	1 part
Godhuma	Triticumaestirum	Seed	1 part
Pippali	Piper longum	Fruit	1 part

Churna Dose and schedule[8,9]

Age group: 2-3years.

Dosage: Group A: 2.5 gm churna with 5 ml ghrita in BD dose.

Group B: 2.5 gm churna with 10 ml ushnodaka in BD dose.

Duration of treatment

The duration of treatment will be for 30 days.

Follow up assessment

Follow up on 45th and 60th day.

Clinical Study

A special case proforma was made for the study, initially vital data like name, age, sex, address, religion; occupation, habitat etc were recorded. A detailed maternal history, birth history, immunization history, dietary history, general examinations, systemic examinations, anthropometry, mile stone etc. were also recorded.

Assessment criteria

Subjective parameters

The assessment is based on improvement in the cardinal sign and symptoms mentioned in Ayurvedic text and assessment will be done with the help of scoring pattern.

1. Arochaka
2. Mukha- Netrashuklata(panduta)

Objective parameters

1. Anthropometric Parameters.
- Height (in cm)
- Weight (in kg)
- Mid arm circumference (in cm)
- Abdominal girth (in cm)
- Triceps skin fold test (in mm)

2. BMI.

Laboratory investigation

1. Serum Total Proteins (gm/dl) - before and after the treatment.
2. Hemoglobin% - before and after the treatment.
3. Thyroid profile if required.

Ethical clearance

This trial has been cleared by institutional ethical committee with Ref. No. SDMCAU/ACA-49/ECA26/15-16.

RESULTS

Table no. 3: Showing the effect of study group on weight.

Group	Weight	Paired Differences					t	df	p value	Remarks
		Mean	SD	SEM	95% Confidence Interval of the Difference					
					Lower	Upper				
Study	**BT-AT**	0.14500	0.06048	0.01352	0.17331	0.11669	10.722	19	0.00	HS
Study	**BT-FU**	0.28500	0.08751	0.01957	0.32596	0.24404	14.565	19	0.00	HS
Control	**BT-AT**	0.07000	0.06569	0.01469	0.10075	0.03925	4.765	19	0.00	HS
Control	**BT-FU**	0.18500	0.07452	0.01666	0.21987	0.15013	11.103	19	0.00	HS

Table no. 4: Showing the effect of study group on height.

Group	Height	Paired Differences					t	df	p value	Remarks
		Mean	SD	SEM	95% Confidence Interval of the Difference					
					Lower	Upper				
Study	**BT-AT**	0.51000	0.72395	0.16188	0.84882	0.17118	3.150	19	0.005	S
Study	**BT-FU**	0.68000	0.80039	0.17897	1.05460	0.30540	3.799	19	0.001	HS
Control	**BT-AT**	0.06000	0.07539	0.01686	0.09529	0.02471	3.559	19	0.002	S
Control	**BT-FU**	0.16000	0.09947	0.02224	0.20655	0.11345	7.193	19	0.000	HS

Table no. 5: Showing the effect of study group on mid arm circumference.

groups	MAC	Paired Differences					t	df	p value	Remarks
		Mean	SD	SEM	95% Confidence Interval of the Difference					
					Lower	Upper				
Study	**BT-AT**	0.01000	0.03078	0.00688	0.02441	0.00441	1.453	19	0.163	NS
Study	**BT-FU**	0.04500	0.06048	0.01352	0.07331	0.01669	3.327	19	0.004	S

Table no. 6: Showing the effect of study group on abdominal girth.

Groups	AG	Paired Differences					t	df	p value	Remarks
		Mean	SD	SEM	95% Confidence Interval of the Difference					
					Lower	Upper				
Study	**BT-AT**	0.02000	0.04104	0.00918	0.03921	0.00079	2.179	19	0.042	NS
Study	**BT-FU**	0.06000	0.08208	0.01835	0.09841	0.02159	3.269	19	0.004	S
Control	**BT-AT**	0.00500	0.02236	0.00500	0.01547	0.00547	1.000	19	0.330	NS
Control	**BT-FU**	0.07500	0.12513	0.02798	0.13356	0.01644	2.680	19	0.015	NS

Table no. 7: Showing the effect of study group on BMI.

Groups	BMI	Paired Differences					t	df	p value	Remarks
		Mean	SD	SEM	95% Confidence Interval of the Difference					
					Lower	Upper				
Study	**BT-AT**	0.09500	0.07592	0.01698	0.13053	0.05947	5.596	19	0.000	HS
Study	**BT-FU**	0.33500	0.14965	0.03346	0.40504	0.26496	10.011	19	0.000	HS
Control	**BT-AT**	0.09000	0.10712	0.02395	0.14013	0.03987	3.758	19	0.001	HS
Control	**BT-FU**	0.25000	0.12354	0.02763	0.30782	0.19218	9.050	19	0.000	HS

Table no. 8: Showing the effect of study group on HB.

Group	HB	Paired Differences					t	Df	p value	Remarks
		Mean	SD	SEM	95% Confidence Interval of the Difference					
					Lower	Upper				
Study	**BT-AT**	0.55500	0.54360	0.12155	0.80941	0.30059	4.566	19	0.000	HS
Control	**BT-AT**	0.11000	0.61593	0.13773	0.39826	0.17826	0.799	19	0.434	NS

Table no. 9: Showing the effect of study group on Total protein.

Group	Total protein	Paired Differences					t	df	p value	Remarks
		Mean	SD	SEM	95% Confidence Interval of the Difference					
					Lower	Upper				
Study	**BT-AT**	0.07500	0.10195	0.02280	0.12272	0.02728	3.290	19	0.004	S
Control	**BT-AT**	0.11500	0.19270	0.04309	0.20518	0.02482	2.669	19	0.015	NS

Table No. 10: Results of Therapy in comparison between study and control group.

Anthropometric parameters	Group	Mean	S.D	S.E	t	p value	Remarks
Weight mean	Study group	0.1450	0.06048	0.01352	3.756	0.001	HS
	Placebo group	0.0700	0.06569	0.01469			
Weight_60day_mean	Study group	0.2850	0.08751	0.01957	3.891	0.000	HS
	Placebo group	0.1850	0.07452	0.01666			
Height mean	Study group	0.5100	0.72395	0.16188	2.765	0.009	NS
	Placebo group	0.0600	0.07539	0.01686			
Height_60day_mean	Study group	0.6800	0.80039	0.17897	2.883	0.006	NS
	Placebo group	0.1600	0.09947	0.02224			
MAC mean	Study group	0.0100	0.03078	0.00688	1.453	0.154	NS
	Placebo group	0.0000	0.00000	0.00000			
MAC_60day_mean	Study group	0.0450	0.06048	0.01352	1.530	0.134	NS
	Placebo group	0.0200	0.04104	0.00918			
AG mean	Study group	0.0050	0.02236	0.00500	1.435	0.159	NS
	Placebo group	0.0200	0.04104	0.00918			
AG_60day_mean	Study group	0.0750	0.12513	0.02798	0.448	0.657	NS
	Placebo group	0.0600	0.08208	0.01835			
TSF mean	Study group	0.0000	0.00000	0.00000	0.0	0.0	NS
	Placebo group	0.0000	0.00000	0.00000			
TSF_60day_mean	Study group	0.0000	0.00000	0.00000	0.0	0.0	NS
	Placebo group	0.0000	0.00000	0.00000			
BMI mean	Study group	0.0950	0.07592	0.01698	0.170	0.866	NS
	Placebo group	0.0900	0.10712	0.02395			
BMI_60day_mean	Study group	0.3350	0.14965	0.03346	1.959	0.057	NS
	Placebo group	0.2500	0.12354	0.02763			
HB mean	Study group	0.5550	0.54360	0.12155	2.423	0.020	NS
	Placebo group	0.1100	0.61593	0.13773			
Totalprotein_mean	Study group	0.1150	0.19270	0.04309	0.821	0.417	NS
	Placebo group	0.0750	0.10195	0.02280			

Table no. 11: Showing Effect of vidarikandadi choorna in study group (Wilcoxon signed rank test).

Group	Parameters	Negative ranks			Positive ranks			Ties	Total	Z Value	P Value
		N	MR	SR	N	MR	SR				
Study	Arochaka	6	3.50	21.00	0	0.00	0.00	14	20	1.000	0.317
Control	Arochaka	3	2.00	6.00	0	0.00	0.00	17	20	0.000	1.000
Study	Mukha Netrashuklata	5	3.00	15.00	0	0.00	0.00	15	20	1.000	0.317
Control	Mukha Netrashuklata	1	1.00	1.00	0	0.00	0.00	19	20	0.000	1.000

Table no. 12: Showing Mann Whitney U Test between the Groups.

Parameters	STUDY GR		CONTROL GR		Z Value	P Value	Remark
	MR	SR	MR	SR			
Arochaka	18.93	378.50	22.08	441.50	1.000	0.317	NS
Mukha Netrashuklata	18.50	370.00	22.50	450.00	1.000	0.317	NS

DISCUSSION

A) Subjective parameters

Arochaka: There was no statistical significance seen but mild improvement of Arochaka was found in 6 children, with no change in 14 children (Z=1.000) (p=0.317) in study group.

There was no statistical significance seen but improvement of Arochaka was found in 3 child, with no change in 17 children (Z=0.000) (p=1.000) in control group.

In the study group (p=0.317) as compared to control group (p=1.000) there is no significant change in the Arochaka, but then the mean improvement was noticed in study group when compared to control group.

Mukha Netra Shuklata: There was no statistical significance seen but mild improvement of Mukha-Netrashuklata was found in 5 children, with no change in 15 children (Z=1.000) (p=0.317) in study group.

There was no statistical significance seen but improvement of Mukha-Netrashuklata was found in 1

child, with no change in 19 children (Z=0.000) (p=1.000) in control group.

In the study group (p=0.317) as compared to control group (p=1.000) There is no significant change in the Mukha Netra Shuklata, but then the mean improvement was noticed in study group when compared to control group.

B) Objective Parameters

Anthropometric Measurements

Weight: The ingredients like Vidarikanda having Madhura rasa, Guru and Snigdhaguna with Madhura vipaka, 85.1% of the carbohydrates; Yava having madhura rasa, Guru guna, 69.3% carbohydrates; Godhuma having Madhura rasa, Guru, snigdha guna and Madhura vipaka with 71.91% carbohydrates; Pippali having Snigdha guna, Madhura vipaka attributes in the brumhana of shareera and thereby helps in the improvement of weight.

Height: The Vidarikanda & Pippali can be attributed to the Rasayana properties that act on srotas which enhance the microcirculation & tissue utilization of body.

Mid Arm-Circumference: There will not be significant increase in the MAC, as in children MAC is because of the subcutaneous fat but as they grow old, it is replaced by muscle bulk. Mid arm circumference is useful to detect malnutrition in young children. Values more than13.5 cm may be considered as normal, while values less than 12.5 cm indicate significant under nutrition. Here the values in both groups were in the normal range.

Abdominal girth: The ingredients of the Churna Pippali having a property of bio-availability that enhances the properties of Vidarikanda, Yava & Godhuma which helps in improving the abdominal girth.

Triceps Skin fold thickness (TSF): TSF in children reaches its maximum level at 1yr of age after which the thickness gradually reduces up to the age of 12yrs. Hence there was no improvement seen in TSF.

Body Mass Index (BMI): As BMI is the outcome of the height and weight so the improvement seen in the BMI.

Haemoglobin(Hb%): The rasayana effect of Vidarikanda & Pippali which harmonizes the function of rasadhatwagni thus promoting the formation of healthy Dhatus including Rakta.

Total Protein (TP): The ingredients like vidarikanda having Crude Proteins - 10.9%, Yava having 11.5% proteins, Godhuma having with 10.7% protein and Deepana, Pachana property of Pippali attributes in the brumhana of shareera and thereby helps in the improvement of total protein.

Probable mode of action of vidarikandadi Churna

Nutrition & Stimulation are the two main factors for prevention & treatment of PEM. Vidarikandadi Churna having a property of Deepana, Paachana, Balya, Brimhaniya, Rasayana Madhura Rasa and Madhura Vipaka which is Vata Shamaka. The Srotoshodhaka property of Pipalli helps in clearance of channels and improves the circulation of Aahara rasa indirectly helps in nourishment of Dhatus means responsible for Uttarottar Dhatu Poshana. Vatanulomaka property of Vidarikanda helps in balance and maintenance of Agni and ultimately causes Samyak Aharpaka.

Vrishya property helps in triglyceride synthesis which is Deha vridhikara Bhava. On the other hand Guru Shita Snigdha and Mridu Gunas are directly responsible for Brimhana effect in body. Rasayana property improves general health and immunity. Jivaniya property maintains equilibrium of Dosha, Dhatu and Malas. Flavone present in Vidarikanda is a free radical scavenger and polyphenol modulate hepatic cholesterol metabolism and reduce inflammation in GIT.

CONCLUSION

Balashosha being a Kapha Pradhana kuposhana janya Vyadhi, Pharmacotherapies like Brimhana, Rasayana have been advocated in the classics for the management of Balashosha. The pradhana lakshanas of Balashosha as mentioned in the classics like, Arochaka and Mukha netra shushkata were observed in the present study. The drug Vidarikandadi Churna contains Vidarikanda, Yava, Godhuma and Pippali shows better results which might be because of the Deepana, Pachana, Brumhana, Balya, Rasayana and Srotoshodhana action. The present study group showed significant response in weight parameter, indicating the accelerated growth. Height was also improved in individuals of both the groups but rate of growth was significantly higher in the study group.

It justifies the effect of Vidarikandadi Churna at Dhatu level by providing nourishment to all the Dhatus. The drug has positive effect on formation of all the dhatus as it potentiates and harmonize dhatvagni functions so that, all dhatus including Mamsa and Meda are formed adequately and thus helps in improving the body mass index and the main laboratory parameters studied were Hb gm% and total protein. The significant increase in hemoglobin and total protein may be due to the rasayana effect of Vidarikanda which harmonizes the function of rasadhatwagni, thus promoting the formation of healthy Dhatus including Rakta. From the study, it is revealed that after completion of treatment schedule, Vidarikandadi Churna with ghrita with sukhoshnaksheer as anupana along with foods as being practiced at home. Showed highly significant results in the management of Balashosha in children when compared to placebo group and remarkable results were obtained in Anthropometric indices and blood parameters in study group.

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