

A CLINICAL STUDY TO EVALUATE THE EFFICACY OF ASHWAGANDHAKSHEER-PAKA AND KSHIRABALA TAILA ABHYANG IN MANAGEMENT OF BALASHOSHA W.S.R. TO PEM

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ABSTRACT

Background-*Balashosha* is the most wide spreading health and nutritional problem among the pediatric population in India and other developing countries. Protein energy malnutrition is a possible condition which may be correlated with *Balashosha*. It affects particularly the preschool children can lead to permanent impairment in later life. PEM is measured in terms of underweight (low weight for age), stunting (low height for age) and wasting (low weight for height). As per WHO, a malnourished child dies at every one second. 47% of the children under three years of age are malnourished over 200 million children in developing countries to more than half of the nearly 12 million under five death in developing countries each year. Lots of attempts have been made to minimize this at National level but these are not sufficient. Indigenous system of medicine especially Ayurveda can play major role in providing solution to this problem. Either due to various diseases or due to excessive indulgence in *Balshoshkarak Nidanas* pathological changes occurs in the body, leading to manifestation of *Balshosha*; in such situations, *Brumhana* and *Balya* therapy is indicated. **Aim-** The present study was undertaken to find out the *Brumhana* effect of *AshwagandhaKsheer Paka* and *Kshirabala Taila Abhyanga* in the management of *Balashosha* in children. **Materials and Methods-** Forty patients were studied and randomly divided into two groups namely Group-A and Group-B with 20 patients in each group. Group-A received *AshwagandhaKsheer Paka* and Group-B received *AshwagandhaKsheer Paka* along with *Kshirabala Taila Abhyanga*. Effect of drugs was observed at the end of sixty days. **Result-** The improvement was more in group B, i.e. the subjects receiving *AshwagandhaKsheer Paka* along with *Kshirabala Taila Abhyanga*. There was good relief of the chief complaints and a trend for improvement was seen in supplementary parameters also. In group-A marked, moderate and mild improvement was observed in 13.34, 72.43% and 14.23% respectively, whereas in group-B, 15.84%, 73.23% and 13.33% 10.93% patients showed. **Conclusion-** It was concluded that consumption of *AshwagandhaKsheer Paka* along with *Kshirabala Taila Abhyanga* is

useful for the management of *Balashosha* in children when compared to only oral medication with *AshwagandhaKsheer Paka*.

Keywords: *AshwagandhaKsheer Paka*, *Kshirabala Taila Abhyanga*, Protein energy malnutrition,

INTRODUCTION

Balshosha or Malnutrition is a major public health problem among the pediatric population in India and other developing countries. Protein energy malnutrition is a possible condition which can be well correlated with *Balashosha*. It affects particularly the preschool children (can lead to permanent impairment in later life. PEM is measured in terms of underweight (low weight for age), stunting (low height for age) and wasting (low weight for height). According to UNICEF Good nutrition is the cornerstone of long life, good health, and proper development. Well-nourished children perform well in school, grow into healthy adults and, in turn, give their children a better start in life. According to National Family Health Survey (NFHS) -3, carried out in 2005-06, 40% of India's children under the age of three are underweight, 45% are stunted and 23% are wasted¹. Almost 11 million children are estimated to die before they reach the age of five; four million of them in the first month of life. In India, almost one out of every 2 children goes to¹bed an empty stomach. Both girls and boys have a similar prevalence of undernutrition. It is more prevalent in rural areas (46%) than in urban population (33%). During the study 20-30% of children are already malnourished, often because they were born with low birth weight. The proportion of undernutrition starts rising after 4-6 months of age because of the introduction of unhygienic food intake, which leads to increase in predisposition to undernutrition.

In the disease *balashosha*² there is obstruction of *rasavaha srotas* by *kapha dosha*³ either due to low immunity status leading to various diseases or infections, due to which excessive indulgence in pathological changes occur in the body, and then the child becomes morbid. So there is inadequate nutrition to the further *dhatus*. The *agni* also becomes weak. The symptoms⁴ like *Shuskata* (Emaciation), *Arochaka* (loss of appetite), *Pratishyaya* (rhinitis), *Jwara* (fever), *Kasa* (cough), *Mukha- Netra-shuklata* (pallor) and *Mukha Snigdhatata* (oedema) are found. In modern science, emaciation of body is due to improper or inadequate nourishment, so the disease caused is called as malnutrition or Protein Energy Malnutrition⁵ (PEM). The World Health Organization (WHO) defines malnutrition as "the cellular imbalance between the supply of nutrients and energy and the body's demand for them to ensure growth, maintenance, and specific functions." Lots of attempts have been made to minimize this at National level but these are not sufficient. Ayurveda can play major role in providing solution to this problem. In such situations, *Dipana* (digestive stimulation) *Rasayana* (rejuvenation), *Balya* (promoting strength) or *Srotoshodhana* (clearing obstruction in the channels carrying nutrients) drugs are indicated. In the present work an attempt has been made to establish the efficacy of the drug *Ashwagandha* for its *Brumhana* effect in the form of *Ksheerpaka* as oral medication and *Kshirabala Taila* in the form of *Abhyanga*

(Massage therapy). The ingredients of both the formulations have the above mentioned properties.

AIMS & OBJECTS

To evaluate efficacy of *Ashwagandha Ksheerpaka* and *Kshirabala Taila Abhyang* in *Balashosha*.

MATERIALS & METHODS

Methods: Forty patients were selected randomly from O.P.D., P.G. Department of Kaumarbhritya, State Ayurvedic College and Hospital Lucknow, that satisfied the inclusion and exclusion criteria. They were randomly divided in two groups namely Group-A and Group-B.

Group A: contain 20 patients, received *AshwagandhaKsheerpaka* orally

Group B: contain 20 patients, received *Ashwagandha Ksheerpaka* orally along with *Kshirabala Taila Abhyang* consecutively for 3 months. Routine diet was recommended.

Assessment based on blood values and clinical features was done before and after the treatment. The results were statistically analyzed and compared in between two groups with the help of Student t-test.

Preparation of Ashwagandha Ksheerpaka-Materials

Powder of Ashwagandha root- 100mg /Kg/day, Milk- 50 ml, Water – 50 ml, Sugar – 1/2 tea spoon – for each serving.

Procedure: Patients were asked to boil milk with *Ashwagandha* powder, sugar and water on low flame till the mixture reduces to 50 ml and drink luke warm

Dosage: 50 ml of *Ashwagandha* milk twice daily

Preparation of Kshirabala Taila-Ksheerbalataila, a compound mentioned in *Sahasra Yoga*, an authentic Ayurvedic formulary of Kerala, contains *Bala mula* processed with Til tail and cow milk. *Kshirabala Taila*, used for the trial was prepared in the pharmacy of State Ayurvedic College Lucknow by concerned experts under the supervision of Department of Rasashashtra and *Bhaishajya kalpana*.

Clinical study was done on 40 patients of 1 to 10 years of age were selected from OPD of P.G. Department of *Kaumarabhritya*, SAC, Lucknow.

A. Inclusion Criteria

Inclusion criteria:

1. Patients as per classical signs and symptoms of *Balashosha*.
2. The children suffering from *Balashosa* on the basis of IAP criteria for diagnosis of PEM

Grade I: Patients with 71 – 80% of expected weight for age,

Grade II: Patients with 61 – 70% of expected weight for age,

Grade III: Patients with 51– 60% of expected weight for age,

Grade IV: Patients with < 50% of expected weight for age.

B. Exclusion Criteria

Patients suffering from

- Secondary malnutrition
- Acute and Chronic diarrhea
- Congenital heart disease, genetic disorders.

- TB and other infectious disease
- Other systemic disorders like DM etc.

C. Investigation

Proper examination of the patient was done with proper history with general and systemic examination at one month interval on cardinal sign and symptoms of *Balashosa* and PEM i.e. *Shuskata* (weight loss), *Arochaka* (loss of appetite), *Pratishyaya* (rhinitis), *Jwara* (fever), *Kasa* (cough), *Mukha- Netrashuklata* (pallor), *Mukha snigdhatata* (oedema), generalized weakness and decline of activity. Hemoglobin percentage and serum protein level were investigated before and after the trial. Other routine investigations were also done to exclude any other disease.

D. Criteria for assessment of patients

The clinical evaluation of the patient was done by following particular.

I. Subjective assessment -Assessment of clinical features of *Balashosa* depending on severity was done on four point scale.

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

A. ASSESSMENT SCALE

Shuskata: (Emaciation)

(IAP Classification)

- G0 – > 80% of expected weight for age,
- G1 – 71-80% of expected weight for age,
- G2 – 61-70% of expected weight for age,
- G3 – < 60% of expected weight for age.

Arochaka (loss of appetite):

- G0 – Normal,
- G1 – Unwilling to take food
- G2 – Unwilling to take food, intake of food decreases
- G3 – Always showing lack of interest to food or taking meal once in a day.

Pratishyaya (rhinitis):

- G0 – Normal, Absence of symptom,
- G1 – Occasional nasal discharge, once in 2 months.
- G2 – Discharge is more frequent during morning and evening, once every month.
- G3 – Discharge all times. Twice or more every month.

Jwara(fever):

- G0 – No fever (Temperature 98.60F),
- G1 – Mild fever (Temperature 98.60-1000F),
- G2 – Moderate fever (Temperature 1000-1020F),
- G3 – Moderate fever (Temperature >1020F).

Kasa (cough):

- G0 – No bout of cough,
- G1 – Intermittent cough or cough only during morning hours,
- G2 – Constant cough, not interfering with sleep or daily activities,
- G3 – Constant or paroxysmal episode of cough interfering with sleep or daily activities.

Mukha- Netrashuklata (pallor)

- G0 – No pallor of face and palpebral conjunctiva.
- G1 – Slightly pale conjunctiva without pallor of face
- G2 – Very pale conjunctiva with apparent facial pallor
- G3 – Pale conjunctiva with pale face and palmer creases

Mukha Snigdhatata (oedema):

- G0 – No oedema
- G1 – Swelling in one particular region like pedal oedema.
- G2 – Oedema in two different sites like pedal and periorbital
- G3 – Generalised oedema.

Generalized Weakness:

- G0 – Normal
- G1 – Patient feels weak after playing, working or doing something continuously
- G2 – Patient shows laziness or disinterested to do anything or to play,
- G3 –Always interested to sleep or bedridden.

Loss of Attentiveness:

- G0 – Child always interested to do some work or to play with friends,
- G1 –Child sometimes disinterested to do any work or play with friends also,
- G2 –Child frequently showing disinterest to do any work or play with friends also,
- G3 – Child always disinterested to do any work and play with friends also.

II. Objective assessment - The objective assessment was done on the basis of the investigation report of the patient and the anthropometric measurement before and after treatment.

Blood Parameters:

Serum albumin

HB%

Anthropometric parameters:

- Assessment of weight gain
- Assessment of height gain
- Assessment of Mid-Upper Arm Circumference (MUAC)

Clinical Assessment of Result

Data was analyzed statistically in terms of mean (M), standard deviation (S.D.). Paired t-test was carried out at the level of p-values 0.05, 0.01 and 0.001.

The clinical study was analyzed after the treatment as hereunder.

- Cure = 100% remission of sign and symptoms,
- Maximum improvement = 75-99% of remission of sign and symptoms,
- Moderate improvement = 50-74% of remission of sign and symptoms,
- Mild improvement = 25-49% of remission of sign and symptoms,
- No improvement = < 25% of remission of sign and symptoms.

Table 1: Effect of Trial Drug Ashwagandha Ksheerpaka on Clinical Features-(Group A, n=20)

Parameters	N	Mean		Dif.	% of Change	SD	SE	p Value
		BT	AT					
Shuskata	16	1.38	0.69	0.69	50.00	0.48	0.12	<0.001
Arochaka	16	1.38	0.75	0.63	45.45	0.50	0.13	<0.01
Pratishyaya	11	1.09	0.55	0.55	50.00	0.52	0.16	<0.01
Jwara	8	1.25	0.50	0.75	60.00	0.46	0.16	>0.1
Kasa	11	1.18	0.73	0.45	38.46	0.51	0.15	>0.1
Mukha- Netra- shuklata	13	1.23	0.62	0.62	50.00	0.51	0.14	<0.01
Mukha snigdhatta	16	1.56	1.00	0.56	36.00	0.51	0.13	<0.01
generalized weakness	11	1.09	0.82	0.27	25.00	0.47	0.14	<0.01
Loss of Attentiveness	16	1.38	0.75	0.63	45.45	0.50	0.13	<0.01

Table 2: Effect of Trial Drugs Ashwagandha Ksheerpaka orally along with Kshirabala Taila Abhyanga on Clinical Features-(Group B, n=20)

Parameters	N	Mean		Dif.	% of Change	SD	SE	p Value
		BT	AT					
Shuskata	14	1.29	0.64	0.64	50.00	0.50	0.13	<0.001
Arochaka	14	1.21	0.71	0.50	41.18	0.52	0.14	<0.01
Pratishyaya	9	1.11	0.56	0.56	50.00	0.53	0.18	<0.01
Jwara	6	1.17	0.50	0.67	57.14	0.52	0.21	>0.1
Kasa	11	1.09	0.73	0.36	33.33	0.50	0.15	>0.1
Mukha- Netra- shuklata	11	1.18	0.64	0.55	46.15	0.52	0.16	<0.01
Mukha snigdhatta	7	1.14	0.57	0.57	50.00	0.53	0.20	>0.1
generalized weakness	14	1.57	1.07	0.50	31.82	0.52	0.14	<0.01
Loss of Attentiveness	14	1.36	0.79	0.57	42.11	0.51	0.14	<0.01

Table 3: Effect of Trial Drug Ashwagandha Ksheerpaka on Laboratory Parameters (Group A, n=20)

Parameters	Mean		Dif.	% of Change	SD	SE	p Value
	BT	AT					
Hb%	11.42	11.80	0.38	3.23	0.53	0.06	<0.01
Sr. Albumin	3.90	4.42	0.52	13.65	0.39	0.06	<0.01
Weight	19.40	21.43	02.03	10.46	4.43	0.52	<0.01
Height	118.63	119.37	0.74	0.61	6.91	0.17	<0.001
Mid arm Circumference	16.18	16.74	0.66	3.53	0.94	0.08	<0.001

Table 4: Effect of Trial Drug Ashwagandha Ksheerpaka orally along with Kshirabala Taila Abhyanga on Laboratory Parameters (Group B, n=20)

Parameters	Mean		Dif.	% of Change	SD	SE	p Value
	BT	AT					
Hb%	11.68	12.05	0.37	3.08	0.51	0.17	<0.001
Sr. Albumin	3.86	4.27	0.41	10.56	0.39	0.13	<0.01
Weight	19.30	21.06	1.76	9.12	4.45	0.59	<0.01
Height	115.70	116.60	1.10	0.77	7.68	0.18	<0.001
Mid arm Circumference	16.02	16.66	0.64	3.93	1.01	0.08	<0.001

Table 5: Comparison of effect of therapy in two groups

Comparison	Mean diff	Q	p Value	Remark
Group A vs Group B	8.974	3.064	P>0.05	NS

DISCUSSION

Effect on clinical features of *Balashosha*

Arochaka is one of the most common features of *Balashosha*. The effect of the drug on score of *Arochaka* in both group A and group B was significant ($p < 0.01$) at 1% level. The effect on *Pratishyaya* after treatment was good in both the groups with 50% relief in each. Paired 't' test after trial shows significant results both the groups ($p < 0.01$). There was fair response to *Jwara* which was 60% in group A and 57.14% of improvement in group B, which shows that both the treatments were equally effective on *Jwara*.

Mukha - Netra swetata is one of the most common features of anemia in malnutrition. As this symptom develops gradually after a long period of malnutrition effect of drug in improving *netra shwetata* is also slow. On after treatment assessment (Table.1,2) it shows good improvement in both the groups with 50.00% improvement in group A and 46.15% in group B. Results of both drugs were statistically significant ($p < 0.01$) The *Ashwagandha Ksheer Paka* acts by its property and improves *rasa* and *rakta dhatwagni* which leads to formation of healthy *rasa dhatu* which in turn nourishes all other *dhatu*; thus *Rakta* is also nourished. *Mukha snigdhta* or *Shotha* (oedema) is one of the important features of *Balashosha*. The edema is mainly either of hypoalbuminemia or other due to anemia. Both the causes are alleviated as total serum albumin and hemoglobin is shown to increase by the trial drug. In group A only 36% of relief was seen after treatment and in group B it was 50%. Statistically the effect was significant in group A and in group B with 'p' value < 0.01 .

Effect on Anthropometric readings-

Weight: The effect of treatment after treatment in Table.1 with *Ashwagandha Ksheerpak* showed a remarkable improvement in weight during successive evaluations ($p < 0.01$). In patients of group B individuals, i.e, patients having *Ashwagandha Ksheerpak* orally along with *Ksheer BalaTail Abhyanga* also weight was increased. ($p < 0.01$). Both the groups showed significant response in weight parameter, indicating the accelerated growth.

Height: Height was also improved in individuals of both the groups but rate of growth was significantly higher in the group B ($p < 0.001$). It strongly justified the effect of *Ashwagandha Ksheerpak* and *Ksheer BalaTail* at *dhatu* level by providing nourishment to all the *dhatu*.

Mid upper arm circumference: Increase in mid upper arm circumference in both groups after treatment was statistically significant ($p < 0.001$). The drug has positive effect on formation of all the *dhatu* as it potentiates and harmonize *dhatuagni* functions so that all *dhatu* including *Mamsa* and *Meda* are formed adequately and thus mid upper arm circumference increases.

Effect on laboratory parameters

The main laboratory parameters studied was Hb gm% and serum albumin as these are disturbed in malnutrition.

Haemoglobin: In present study the mean Hb of patients in both groups was low; the mean being 11.42gm% in group A and 11.68 gm% in group B. After treatment, mean gain in Hb in group A was 0.38gm%, while in group B it was 0.37 gm % (Table.4). statistically the results are significant in group A ($p < 0.01$) and highly significant ($p < 0.001$) in group B both the groups. The significant increase in hemog-

lobin is due to *rasayana* effect of *Ashwagandha* which harmonizes the function of *rasadhatwagni*; thus promoting the formation of healthy *Dhatu*s including *Rakta*.

Serum Albumin: Serum albumin is a good indicator of protein malnutrition and is usually low in malnourished children. In present study mean serum albumin in group A was 3.90 and in group B it was 3.86 gm. After treatment a gain of 0.52 gm in group A and 0.41 gm in group B was observed. The gain was statistically significant in both the groups ($p < 0.01$).

As shown above, group 2 showed better results in some parameters. Statistically intergroup difference as shown by unpaired 't' test is insignificant showing equal efficacy of therapy in both groups in curing various clinical features. ($P > 0.05$)

Discussion regarding probable mode of action of drug

Since the *Balashosha* is produced as a result of *agnimandya*, *srotorodha* and improper nutrition of *dhatu*s and the predominance of *Kapha* in initial phase with *Vata* dominating at later stage; drug would have been acted on all these steps and *doshas*. *Ashwagandha* is having *sitaVirya* and also having *Balya* and *Rasayana* properties. It is favorable in childhood by its *Mridu*, *Balya*, *Brimhana* and *Rasayana* action on *dhatu*s. *Balya* and *Brimhana* drugs provide the revitalizing strength to the body which is ailing due the chronic disease and increases the production of healthy *dhatu*s in the body. *Ashwagandha* is used as *Rasayana* since the ancient time especially for children in the management of malnourishment.^{6,7} *Ashwagandha* contains very active constituents called with anolides, which are accountable for all of *Ashwagandha*'s medicinal uses.

Growth and development is the main milestone of childhood. *Ashwagandha Ksheerpaka* accelerates the growth, development and immunity of growing child. Cow milk also contains all the elements necessary for the growth and nutrition of bones, nerves, muscle and other tissues of the human body.

Also *Ksheerbalatailaabhyanga* showed upgraded effect on the relief of clinical features as well as in laboratory figures when used along with *Ashwagandha Ksheerpaka*. A study from USA and similar study from Norway showed that the massage therapy improved fine and gross motor functioning, self-care and mobility in children with CP.⁸ Improved immune function has been reported in one massage study,⁹ showing increased number and activity of natural killer cells, which have the potential to destroy viral cells.¹⁰ Massage therapy has been shown to decrease stress hormone (cortisol) levels.¹¹ Several studies have reported that massage leads to enhanced alertness, as shown by increased cognitive scores in preschool children.¹²

CONCLUSION

From the study it is revealed that after completion of treatment schedule, *AshwagandhaKsheer Paka* oral therapy along with *Kshirabala Taila Abhyanga* showed highly significant results in the management of *Balashosha* in children when compared to only oral medication with *AshwagandhaKsheer Paka*, although remarkable results were obtained in Anthropometric indices and blood parameters in both the groups. Intergroup difference as shown by unpaired 't' test is insignificant showing equal efficacy of therapy in both groups in curing various clinical features. 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* and Protein Energy Malnutrition.

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