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A Randomized Controlled Trial of *Godanti Bhasma* against *Balaposhaka Churna* in Management of *Balashosha* w.s.r. to Protein Energy Malnutrition

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Abstract

Background and Objective: Today Pediatric malnutrition constitutes a major public health problem in India and other countries of third world. Lots of attempts have been made to minimize this at National level but these are not sufficient. Therefore, Indigenous system of medicine especially Ayurvedic rasashastra can play major role in providing health to children.

Design: A Randomized controlled trial was conducted.

Methods: Thirty participants were selected from nearby rural Govt. U. P. School Velliyakulam (Chertala) that satisfied the inclusion and exclusion criteria. They were randomly divided in two groups. The trial drug *Godanti bhasma* is administered in study group and *Balaposhaka churna* in control group for duration of one month. Follow up was taken after completion of medicine and after three months. 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.

After the treatment weight, height, mid upper arm circumference and S. Albumin was significantly increased in both the groups. In symptomatic evaluation both the drugs were significantly effective, but the trial drug was more effective on height gain and Serum Albumin than the control drug.

Keywords

Godanti bhasma, Protein energy malnutrition, *Balaposhaka churna*

Greentree Group

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INTRODUCTION

Today nutritional deficiencies constitute a major public health problem in India and other countries of third world. The severe forms of Kwashiorkor and Marasmus are the leading killers of our pediatric population. In India around ¾th of our pediatric population is suffering from one or other nutritional deficiencies. About 75 – 80 % of hospitalized children suffer from some degree or type of malnutrition. Around 25% of the pediatric beds are occupied by patients whose major problem is malnutrition or in whom malnutrition is indirectly responsible for hospitalization.

Lots of attempts have been made to minimize this at National level. To achieve this immunization plans and milk distribution or mid day meal to school going children alone is not sufficient. Therefore Indigenous system of medicine especially *Ayurveda* can play major role in providing health to children.

The word *Balashosha* is formed from two separate words i.e., *Bala* and *Shosha*. *Bala* means a child and *Shosha* is used for emaciation of body and its *dhatus*[1]. Thus *Balashosha* can be derived as "*Balasya Shosha Balashosha*" i.e. 'a condition in which child is emaciated. *Ashtanga Hridyakara* mentions the following clinical features of *Balashosha*[2].

· *Aruchi* (loss of appetite)

· *Pratishayaya* (coryza)

· *Jwara* (pyrexia)

· *Kasa* (cough)

· *Shosha* (emaciation)

· *Shukla mukha* (paleness of face)

· *Shukla netra* (pallor in eyes)

In Ayurvedic *Rasasastra* text *Rasamrutam (5/7)*[3], *Godanti bhasma* (a mineral preparation) is mentioned to beneficial to cure *Balashosha*. *Godanti* is transparent to white gray colored mineral used in *Rasasastra*. It is mentioned in Rasa classics after 19th century first time in *Rasatarngini* by *Sadanand Sharma*[4]. This has *shita* (cool) quality, useful in *pittajwara*, chronic fever, general weakness, loss of appetite, headache, cough, dyspnoea.Also it cures Headache, fever, pthiasis, cough, Anemia, burning sensation and other pitta diseases.

Also, in previous research done at Regional Research Centre Bangalore, *Balaposhaka churna* made from *Aswagandha*, *Shatavari*, *Amalaki* found to be effective in management of *Balashosha* in dose of 5gm BD.

The present study was aimed to find the effectiveness of *Godanti bhasma* in comparison with *Balaposhaka churna* in Management of *Balashosha* (Protein Energy Malnutrition) in 30 numbers of patients from

the Govt. UP School, Velliyakulam, Chertala which is situated in the rural costal part of Kerala during 2010 to 2012.

DRUG REVIEW-

Godanti is a transparent to white gray colored mineral used in *Rasasastra*. It is mentioned in Rasa classics after 19th century, and first time in the text *Rasatarngini* by *Sadanand Sharma.* So, not much literature about *Godanti* is available in *Rasa* classics.

Godanti is having only four synonyms. It is colourless, white gray to yellow with Chemical composition - $CaSO_4$, 2 H_2O. Some prefer to call this as *Godanti*-hartal which is not correct as there is no relation to *Talaka* (arsenic trisulphide) or even Arsenic[5].

Godanti should be in flakes, with layers that can be separated with difficulty, smooth, lustrous white and translucent[6]. *Shodhana* of *Godanti* is done by *swedana* method in Dolayantra. By doing *swedana* in Dolayantra for 1 ½ hours suspended amidst lemon juice or juice of dronapuspi (lucas aspera), *Godanti* gets purified[7].

Two methods have been mentioned to prepare *Godanti bhasma*. In first method, enclose the pieces of *Godanti* in *Sharava* and give *sadharana puta* and in second method make *chakrikas* of *Godanti* by triturating *Godanti* powder in *Kumari swarasa* and then give *gajaputa*.[8]

Balaposhaka churna-

Balaposhaka churna was obtained from CCRAS Kolkata in which there are three ingredients, all in equal proportions. Ingredients of *Balaposhaka churna* are *Aamalaki*, *Shatavari* and *Aswagandha*, which are used to treat *Balashosha* in the dose of 5gm twice daily with plain water. Clinical trials of *Balaposhaka churna* were conducted by Regional Research Centre Banglore in school children suffering from *Balashosha* and this *churna* was found to have good results.

Aamalaki consists of pericarp of dried mature fruits of *Emblica officinalis. Aamalaki* is pancharasatmaka i.e. having *Amla, Kashaya, Madhura, Tikta and Katu rasa* with *Ruksa and Laghu guna* and *sita Virya*. *Aamalaki* is *Tridoshaghna, Vrsya, Rasayana and Cakshusya* in action[9].

Shatavari is tuberous roots of *Asparagus recemosus* (Fam. Liliaceae). *Shatavari* is *Vrshya, shukraja, Balya, Medhya, Rasayana, Kaphavataghna* in action with *Madhura and Tikta* rasa, *Snigdha and Guru gunas* and also having *sita Virya*[10].

Aswagandha is dried mature roots of *Withania somnifera* (Fam. Solanaceae). *Aswagandha* is

having *Tikta, Kasaya* rasa with *Laghu guna* and *Usna Virya*. It is *Vatakaphaghna, Balya, Rasayana and Vajikarana* in action[11].

All the three ingredients are rasayana and balya in action with tridoshaghna and mainly vata*kapha*ghna property, which is useful in treating *kapha* and *ama rasa janya* obstruction of *rasavaha strotasa*.

Pharmaceutical Study

Godanti Shodhana[12] (*Swedana* in *Dola yantra*)

Procedure:

One kg *Godanti* pieces was taken and kept in a piece of cotton cloth and a *Pottali* was prepared. An iron rod was introduced at the tip of the *Pottali* and it was hanged in steel vessel. Sufficient amount of *Dronapushpi swarasa* was added to dip the *Pottali* completely.

The vessel was kept on the gas stove. The small amount of *Dronapushpi swarasa* was added time to time in sufficient quantity to dip the *Pottali* completely. *Mandagni* was given for one and half hours. Then *Pottali* was taken out. The obtained *Godanti* was subjected in sunlight to dry.

Observations:

Godanti was White with blackish tint in colour in crystal form and lusterous in nature before *Shodhana*. After drying *Godanti* became Greenish White in colour.

- Total time taken for *Swedana* : 1 ½ hours
- Weight of *Godanti* before purification : 1 kg
- Weight of Shuddha *Godanti* : 990 gm
- Weight loss : 10 gm

Marana* of *Godanti[13]

Reference: *Rasatarangini* 11/240

Procedure:

Pieces of Shuddha *Godanti* was kept in an earthen saucer and the saucer was closed by another earthen saucer of same size(*Sharava)* and junction was sealed by double folded mud smeared cloth and allowed for complete drying.

Then that closed earthen saucer (*Sharava samputa*) was subjected to *Sadharana puta(Varaha puta* with 500 cow dung cakes) for incineration.

After self cooling the *Sharava samputa* was taken out and opened.

The material was collected and ground to form fine *bhasma*.

Observations :

Weight of *Godanti* pieces	: 990gm
Weight of *Godanti bhasma*	: 900gm
Colour	: White
Touch	: Smooth

Taste : Tasteless

Odour : Odourless

Bhasma parikshas :

- Varna : white
- Rekhapurnatwa : +ve
- Varitaratwa : +ve
- Slakshnatwa : +ve

Balaposhaka churna

Reference - Formulation of regional research centre,Kolkata

Ingredients -

1. Dried fruit of *Aamalaki*(*Terminalia chebula*) : 1kg
2. Dried root of *Shatavari*(*Asparagus racemosus*) : 1kg
3. Dried root of *Aswagandha*(*Withania somnifera)* : 1kg

1. Evaluation on classical analytical parameter.[14]

Table.1 Organoleptic study results

Sr No.	Organoleptic Parameter	Properties
1.	Colour	White
2.	Taste	Tasteless
3.	Touch	Smooth and fine
4.	Odour	Odourless
5.	*Rekhapurnatva*	+ve
6.	*Varitaratva*	+ve
7.	*Slakshanatva*	+ve
8.	*Mrudatva*	+ve
9.	*Niswadu*	+ve

2. Evaluation on modern analytical parameters[15]

Procedure:

Above ingredients were taken separately one by one in Hammer mill and made Yavkut powder. Then it was transferred into Cone mill to make fine powder. All the three *churnas* mixed well.

Analytical Study

Godanti bhasma samples were subjected for analysis by employing two different kinds of parameters.

AIMS AND OBJECTIVES

1. To evaluate efficacy of *Godanti bhasma* in *Balashosha.*
2. To compare efficacy of *Godanti bhasma* against *Balaposhaka churna* in management of *Balashosha*.

Table.2 Physico-chemcial Parameters

Sr.No.	Parameters	Values		
		Godanti Raw	*Shuddha Godanti*	*Godanti bhasma*
1.	Calcium as Ca+	33.38% w/w	32.15% w/w	33.22% w/w
2.	Calcium oxide as CaO	46.74% w/w	45.01% w/w	46.51% w/w
3.	Sulphate group	16.40% w/w	24.30% w/w	54.22% w/w
4.	Lead	0.0785ppm	-	-
5.	Arsenic	0.0003ppm	-	-
6.	Cadmium	Nil	-	-
7.	Loss on drying	-	-	0.4390% w/w
8.	Ash value	-	-	98.35% w/w
9.	Acid insoluble ash	-	-	3.199% w/w
10.	Water soluble ash	-	-	23.983% w/w
11.	pH	-	-	6.21

MATERIALS AND METHODS

Study Design-

The study was Randomized Controlled Trial.

Approval No.- IEC/108/2010

Setting for the study:

1. Govt. Ayurveda College,Tripunithura.

2. Govt. UP School, Velliyakulam, Dist-Chertala, Kerala

Study Population: Diagnosed cases of *Balashosha* (PEM) from Govt. UP School, Velliyakulam, Chertala satisfying inclusion and exclusion criteria.

Sample size: 30

Selection of objects: As per inclusion and exclusion criteria

Period of study: 18 months

Inclusion criteria:

Patients as per signs and symptoms of *Balashosha* as per classical reference

*Age - 5-12yrs

*Sex - both male and female

*1st and 2nd degree PEM

Exclusion criteria:

Known cases of

- Secondary malnutrition
- Acute and severe diarrhea
- 4th degree PEM
- TB and other infectious disease
- Other systemic disorders like DM etc.
- H/o low birth weight

Table 3 Treatment Schedule:

Particulars	Control group	Trial group

Sample size	15	15
Drug	*Balaposhaka churna*	*Godanti bhasma*
Form	Powder	*Bhasma* (Fine powder)
Anupana	Water	Water
Diet	Standard diet	Standard diet
Duration	1 Month	1 Month
Dose	5 gm BD	4mg/kg body wt. BD

Follow up: 3 months after completion of treatment.

Assessment:

Assessment was done on the basis of the patient proforma- based on subjective and objective parameters.

Clinical features assesement

Assessement of clinical features of *Balashosa* depending on severity was done on four point scale.

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

Arochaka

- Normal appetite 0
- Unwilling to take food 1
- Unwilling to take food, intake of food decreases 2
- No interest to take food 3

Jwara

- No fever, temp. 98- 99^{o}F -0
- Either mild fever, Temp. 99-100 ^{o}F/frequency 1episode/15 days 1
- Either moderate fever, Temp100-102^{o}F or Frequency 2 episode/15 days 2
- Either high fever, Temp>102^{o}F or frequency more Than 2 episode/15 days 3

Pratishyaya

- No nasal discharge or no pratishyaya 0
- Either nasal discharge only in morning 1
- Either nasal discharge both in morning and evening 2
- Continuous nasal discharge 3

Mukha shwetata

- No facial pallor 0
- Mild facial pallor with intact luster 1
- Facial pallor with lost luster 2
- Severe facial pallor with pale palmer creases 3

Netra shwetata

- No pallor of palpebral conjunctiva 0

- Slightly pale conjunctiva without pallor of face 1
- Very pale conjunctiva with apparent facial pallor 2
- Pale conjunctiva with pale face and palmer creases 3

Shotha

- No oedema 0
- Swelling in one particular region like pedal oedema 1
- Oedema in two different sites like pedal and periorbital 2
- Generalised oedema 3

Anthropometric parameters:

Assessment of weight gain

Assessment of height gain

Assessment of Mid-Upper Arm Circumference (MUAC)

Blood Parameters:

Serum albumin

RESULTS AND DISCUSSION

1. Effect of therapy on Hb %

HB%

TLC and DLC

These investigations were carried out at the Krishna Laboratory, Chertala.

Table..4 Effect of therapy on HB%

Group	N	Mean score		% of Increase	S.E.	t	p
		B.T.±SD	A.T.±SD				
Trial	**15**	**11.45±0.83**	**11.83 ±0.90**	**3.23**	**0.10**	**3.6902**	**<0.01**
Control	**15**	**11.69±0.79**	**12.05 ±0.63**	**3.07**	**0.08**	**4.7309**	**<0.001**

Table.5 Effect of therapy on HB% on follow up

Group	N	Mean score		% of Increase	S.E.	t	P
		B.T.±SD	A.F. ±SD				
Trial	**15**	**11.45±0.83**	**11.97±0.79**	**4.54**	**0.10**	**5.4611**	**<0.001**
Control	**15**	**11.69±0.79**	**12.29±0.69**	**5.04**	**0.10**	**5.6336**	**<0.001**

2. Effect of therapy on WBC

Table.6 Effect of therapy on WBC after treatment

Group	N	Mean score		% of Increase	S.E.	t	P
		B.T. ±SD	A.T. ±SD				
Trial	**15**	**10580±1310**	**10580±1284**	**0**	**169.59**	**0**	**>0.1**

Control	**15**	**10353±1807**	**14773±1879**	**42**	**4835**	**0.914**	**>0.1**

Table.7 Effect of therapy on WBC on follow up

Group	N	Mean score		% of Increase	S.E.	t	P
		B.T. ±SD	A.F. ±SD				
Trial	**15**	**10580±1310**	**11013±863**	**4.09**	**217.71**	**1.9904**	**<0.1**
Control	**15**	**10353±1807**	**10406±821**	**0.51**	**318.91**	**0.1672**	**>0.1**

3. Effect of therapy on Sr. albumin

Table.8 Effect of therapy on Albumin after treatment

Group	N	Mean score		% of Increase	S.E.	t	p
		B.T. ±SD	A.T. ±SD				
Trial	**15**	**3.88±0.27**	**4.29±0.52**	**10.56**	**0.11**	**3.731**	**<0.01**
Control	**15**	**3.97±0.23**	**4.05±0.45**	**2.01**	**0.12**	**0.6601**	**>0.1**

Table.9 Effect of therapy on Albumin on follow up

Group	N	Mean score		% of Increase	S.E.	t	p
		B.T. ±SD	A.F. ±SD				
Trial	**15**	**3.88±0.27**	**4.41±0.29**	**13.65**	**0.06**	**8.366**	**<0.001**
Control	**15**	**3.97±0.23**	**4.23±0.30**	**6.54**	**0.08**	**3.1889**	**<0.01**

4. Effect of therapy on weight

Table.10 Effect of therapy on Weight after treatment

Group	N	Mean score		% of Increase	S.E.	t	p
		B.T. ±SD	A.T. ±SD				
Trial	**15**	**19.40±4.95**	**21.17±4.05**	**9.12**	**0.59**	**2.9978**	**<0.01**
Control	**15**	**20.27±3.84**	**21.03±3.41**	**3.79**	**0.21**	**3.717**	**<0.01**

Table. 11 Effect of therapy on Weight

Group	N	Mean score		% of Increase	S.E.	t	p
		B.T. ±SD	A.F. ±SD				
Trial	**15**	**19.40±4.95**	**21.43±4.00**	**10.46**	**0.52**	**3.878**	**<0.01**
Control	**15**	**20.27±3.84**	**21.87±3.45**	**7.89**	**0.17**	**9.387**	**<0.01**

5. Effect of therapy on height

Table. 12 Effect of therapy on Height after treatment

Group	N	Mean score		% of Increase	S.E.	t	p
		B.T. ±SD	A.T. ±SD				
Trial	15	115.67±7.74	116.17±7.59	0.43	0.15	3.24	<0.01
Control	15	118.63±7.01	118.73±7.0	0.08	0.07	1.381	>0.1

Table. 13 Effect of therapy on Height on follow up

Group	N	Mean score		% of Increase	S.E.	t	p
		B.T.± SD	A.F. ± SD				
Trial	15	115.67±7.74	116.57±7.62	0.77	0.18	4.894	<0.001
Control	15	118.63±7.01	119.37±6.89	0.61	0.10	7.642	<0.001

6. Effect of therapy on Mid Upper arm Circumference (MUAC)

Table.14 Effect of therapy on MUAC after treatment

Group	N	Mean score		% of Increase	S.E.	t	p
		B.T.± SD	A.T. ± SD				
Trial	15	16.03±1.06	16.27±1.03	1.43	0.08	2.824	<0.05
Control	15	16.17±0.99	16.30±0.92	0.80	0.08	1.739	>0.1

Table.15 Effect of therapy on MUAC on follow up

Group	N	Mean score		% of Increase	S.E.	t	p
		B.T. ± SD	A.F. ± SD				
Trial	15	16.03±1.06	16.67±0.94	3.93	0.08	8.2642	<0.001
Control	15	16.17±0.99	16.73±0.88	3.52	0.08	6.859	<0.001

7. Effect of therapy on *AROCHAKA*

Table.16 Effect of therapy on *Arochaka* after treatment

Group	N	Mean score		% of Relief	S.E.	t	p
		B.T.± SD	A.T. ± SD				
Trial	15	1.27±0.59	0.60±0.63	52.75	0.19	3.567	<0.01
Control	15	1.73±0.59	1.40±0.51	19.07	0.19	1.783	<0.1

Table.17 Effect of therapy on *Arochaka* on follow up

Group	N	Mean score		% of Relief	S.E.	t	p
		B.T.± SD	A.F. ± SD				
Trial	15	1.27±0.59	0.07±0.26	94.48	0.17	6.873	<0.001

Control	**15**	**1.73±0.59**	**0.87±0.64**	**50.28**	**0.24**	**3.66**	**<0.01**

8. Effect of therapy on *JWARA*

Table.18 Effect of therapy on *Jwara* after treatment

Group	N	Mean score		% of Relief	S.E.	t	p
		B.T.± SD	A.T. ± SD				
Trial	**15**	**0.20±0.41**	**00±0.00**	**100**	**0.11**	**1.87**	**<0.1**
Control	**15**	**0.40±0.51**	**0.20±0.41**	**50**	**0.11**	**1.870**	**<0.1**

Table.19 Effect of therapy on *Jwara* on follow up

Group	N	Mean score		% of Relief	S.E.	t	p
		B.T.± SD	A.F. ± SD				
Trial	**15**	**0.20±0.41**	**0.07±0.26**	**65**	**0.09**	**1.46**	**>0.1**
Control	**15**	**0.40±0.51**	**0.07±0.26**	**82.50**	**0.13**	**2.645**	**<0.05**

9. Effect of therapy on *PRATISHYAYA*

Table.20 Effect of therapy on *Pratishyaya* after treatment

Group	N	Mean score		% of Relief	S.E.	t	p
		B.T.± SD	A.T. ± SD				
Trial	**15**	**0.60±0.83**	**0.27±0.46**	**55**	**0.13**	**2.645**	**<0.05**
Control	**15**	**0.67±0.62**	**0.53±0.52**	**19.40**	**0.13**	**1.00**	**>0.1**

Table.21 Effect of therapy on *Pratishyaya* on follow up

Group	N	Mean score		% of Relief	S.E.	t	p
		B.T.± SD	A.F. ± SD				
Trial	**15**	**0.60±0.83**	**0.13±0.35**	**78.33**	**0.17**	**2.824**	**<0.05**
Control	**15**	**0.67±0.62**	**0.27±0.46**	**59.70**	**0.13**	**3.055**	**<0.01**

10. Effect of therapy on *MUKHA SWETATA*

Table.22 Effect of therapy on *Mukha swetata* after treatment

Group	N	Mean score		% of Relief	S.E.	t	p
		B.T.± SD	A.T. ± SD				
Trial	**15**	**1.27±0.59**	**0.60±0.63**	**52.75**	**0.19**	**3.567**	**<0.01**
Control	**15**	**1.73±0.70**	**1.27±0.59**	**27.16**	**0.13**	**3.5**	**<0.01**

Table.23 Effect of therapy on *Mukha swetata* on follow up

Group	N	Mean score		% of Relief	S.E.	t	p
		B.T.± SD	A.F. ± SD				
Trial	15	1.27±0.59	0.07±0.26	94.48	0.17	6.873	<0.001
Control	15	1.73±0.70	0.67±0.49	61.84	0.18	5.87	<0.001

11. Effect of therapy on *NETRA SWETATA*

Table.24 Effect of therapy on *Netra swetata* after treatment

Group	N	Mean score		% of Relief	S.E.	t	p
		B.T.± SD	A.T. ± SD				
Trial	15	1.53±0.83	0.80±0.68	47.71	0.15	4.784	<0.001
Control	15	1.73±0.59	1.40±0.51	19.07	0.19	1.783	<0.1

Table.25 Effect of therapy on *Netra swetata* on follow up

Group	N	Mean score		% of Relief	S.E.	t	p
		B.T.± SD	A.F. ± SD				
Trial	15	1.53±0.83	0.40±0.51	73.85	0.26	4.431	<0.001
Control	15	1.73±0.59	0.87±0.64	50.28	0.24	3.66	<0.01

12. Effect of therapy on *SHOTHA*

Table. 26 Effect of therapy on *Shotha* after treatment

Group	N	Mean score		% of Relief	S.E.	t	P
		B.T.± SD	A.T. ± SD				
Trial	15	0.67±0.62	0.47±0.52	29.85	0.11	1.870	<0.1
Control	15	0.40±0.51	0.20±0.41	50	0.11	1.870	<0.1

Table.27 Effect of therapy on *Shotha* on follow up

Group	N	Mean score		% of Relief	S.E.	t	p
		B.T.± SD	A.F. ± SD				
Trial	15	0.67±0.62	0.13±0.35	79.10	0.13	4.0	<0.01
Control	15	0.40±0.51	0.07±0.26	82.5	0.13	2.645	<0.05

DISCUSSION

Effect on Anthropometric readings-

Weight:

The effect of treatment after tratment in Table.10 and after follow up in Table.11 with *Godanti bhasma* in the trial group showed a remarkable improvement in

weight during successive evaluations ($p<0.01$). In patients of control group individuals weight was increased due to *Balaposhaka churna* and specific dietary advice. Both the trial drug and control drug efficacy was found to be highly significant, response indicating the accelerated growth. On comparing both the groups, effect of trial drug was statistically not better than control group.

Height:

Height was also improved in individuals of both the groups but rate of growth was significantly higher in the trial group when the comparison was made after treatment which is mentioned in Table.12 and after follow up in Table.13. The trial drug showed its efficacy with highest level of significance by increasing the height ($p<0.05$). It strongly justified the effect of *Godanti bhasma* at dhatu level by providing nourishment to all the *dhatus* with its specific potential action on *Asthi dhatu*. But in after follow up study, height gain in both the group was same and was statistically insignificant on comparing both groups. So, In the after follow up study, effect of *Godanti bhasma* on height was not better than *Balaposhaka churna*. But early effect on height in trial group was may be due to calcium supplement which is present in *Godanti*.

Mid upper arm circumference:

Increase in mid upper arm circumference in trial group after treatment was statistically significant ($p <0.05$), but in control group effect was statistically insignificant in Table. 14. After follow-up, effect of both medicines in both the groups mentioned in Table.15 was highly significant ($p<0.001$). Intergroup difference was statistically insignificant which pointed towards equal efficacy of drugs on MUAC. The drug has positive effect on formation of all the *dhatus* as it potentiates *agni*, relieves obstruction of *srotasa* and harmonize *dhatuagni* functions so that all *dhatus* including *Mamsa* and *Meda* are formed adequately and thus mid upper arm circumference increases.

Effect on clinical features of *Balashosha*

1. *Arochaka*:

Arochaka is one of the most common features of *Balashosha*. The effect of the drug on severity score of *Arochaka* in trial group was initially significant at 1% level but the response improved on follow up study which is significant at 0.1% level(Table.16 and 17). In control group results after treatment were statistically significant

at 10% level and after follow up results were significant at 1% level.

2. *Jwara*:

There was good response to *Jwara* from the very beginning which was 100% in trial group. And only 50% of improvement was observed in control group. Intergroup difference was statistically insignificant which is mentioned in Table.18 and 19, which shows that both the treatments were equally effective on *Jwara*. As the *Jwara* is produced due to Agnimandya, *ama* and obstruction of *rasavaha srotas*, it is relieved with *dipana*, *amapachana* and removal of *srotorodha* by *Jwaraghna* properties of drug compound.

3. ***Pratishyaya***:

After treatment effect mentioned in Table.20 was good in trial group with 55% relief whereas only 19.40% relief was seen in control group. At the end, in Table.21 on follow up overall relief of 78.33% was seen in trial groups against 59.70% in control group. Paired't' test after follow-up shows significant results in trial group ($p < 0.05$) as well as in control group ($p < 0.01$) . Intergroup difference as shown by unpaired 't' test is insignificant showing equal efficacy of drug in curing *pratishyaya*.

4. *Mukha swetata*:

On after treatment assessment (Table.22) *Mukha shwetata* shows good improvement in both the groups with 52.75% improvement in trial group and 27.16% in control group. On follow up results of both drugs were statistically highly significant with 94.48% improvement in trial group and 61.84% improvement in control group(Table.23). Statistical analysis of intergroup difference shows insignificant result reflecting same effect of both the drugs on *Mukha shwetata.*

5. Effect of therapy on *Netra swetata*:

Netra shwetata is one of the most common feature in both groups incidence 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. 47.71% improvement after treatment and an overall 73.85 % improvement after follow up was noticed in trial group. In Table.24 and 25 control group showed only 19.07% relief in first month and 50.28% of relief was there on follow up study. On the other hand relief in trial group was statistically highly significant ($p < 0.001$) as compared to significant relief ($p<0.01$) in control group. The *Godanti bhasma* acts by its property and improves rasa and rakta dhatwagni

which leads to formation of healthy rasa dhatu ehich in turn nourishes all other *dhatus*; thus *Rakta* is also nourished.

6. *Shotha*:

In trial group only 29.85% of relief was seen after treatment and in control group it was 50%(Table.26). On follow up, relief mentioned in Table.27 was 79.10% in trial group and 82.5% in control group. Statistically the effect was significant with 'p' value in trial group <0.01 and in control group <0.05 . Statistics of intergroup difference shows insignificant result reflecting same effect of both the drugs on *Shotha*. 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 *Godanti bhasma*.

Effect on laboratory parameters

The main laboratory parameters studied was Hb gm% and serum albumin as these are disturbed in malnutrition. In addition TLC and DLC were also done to check out that, whether the drug is altering normal parameters or not.

Haemoglobin:

In present study the mean Hb of patients in both groups was low; the mean being 11.45 gm% in trial group and 11.69 gm% in control group. After treatment, mean gain in Hb in trial group was 0.38gm%, while in control group it was 0.36 gm%(Table.4). On follow up, mean gain was0.52gm% in trial group and 0.60 in control group (Table.5). Statistically the results are significant in both the groups. The significant increase in hemoglobin is due to *Deepana* effect of *Godanti bhasma* which harmonizes the function of *Jatharagni* as well as *dhatwagni*; thus promoting the formation of healthy *Dhatus* 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 trial group was 3.88 and in control group it was 3.97 gm. After treatment a gain of 0.41 gm in trial group and 0.07 gm in control group was observed, the gain was statistically significant in trial group (p <0.01) whereas in control group it was insignificant (p>0.10) which is mentioned in Table.8. On follow up, mean gain in serum albumin was 0.53 in trial group and 0.26 in control group, the gain was statistically highly significant at 0.1% level in trial group whereas it was

significant at 1% level in control group(Table.9). Intergroup difference in serum albumin gain is statistically significant ($p < 0.01$) indicating that drug have positive effect on serum albumin level in malnutrition.

Discussion regarding probable mode of action of drug

As the *Balashosha* is produced as a result of *agnimandya, srotorodha* and improper nutrition of *dhatus* 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*.

Godanti is having sita *Virya* and also having Balya and Dipana properties. The *Sita Veerya* is favorable in childhood by its *Mridu, Balya Brimhana* and *Rasayana* action on *dhatus. Dipana* property of *Godanti* is responsible for relieving Agnimandya, which is initial step of samprapti of *Balashosha*. Thus it breaks the pathogenesis of *Agnimandya janya srotorodha* which is root cause of *Balshosha.*

Balya drugs provides the revitalizing strength to the body which is ailing due the chronic disease and increases the production of healthy *dhatus* in the body. *Deepana* effect potentiates the *Agni* and increases the digestive power; also by these actions eliminate the *Ama* and S*rotorodha* produced by it.

CONCLUSION

Present study reflects that both regimens- simple standard diet with drug has good outcome on anthropometric index of children with malnutrition.

In this Study, trial drug and control drug both showed marked improvement on all parameters of *Balashosha*. On Clinical features, Anthropometric indices and blood parameters, trial drug *Godanti bhasma* as well as control drug *Balaposhaka churna* had significant improvement.

But on height gain, trial drug showed highly significant results when compared with control drug. Also, total serum albumin significantly increased up to normal level by trial drug "*Godanti bhasma*" when compared with control drug.

Trial drug was better than control drug in other aspects like, it was economic, had no problem of palatability, dose was very small, it was very easy to prepare & store, and had no expiry date.

No adverse effects of the drug therapy were observed during study.

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