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A comparative study on the effectiveness of *Pathadi churna* and Protein powder in *Karshya* (Undernutrition) among preschool children

Research Article

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Abstract

Introduction: Ayurveda depicts a disease named '*Karshya*' which goes hand in hand with the clinical entity 'Under-nutrition' in contemporary science. Aim & Objectives: The present study aimed to compare the efficacy of '*Pathadi churna'* and Protein Powder as oral administration in preschool children suffering from Under-nutrition. Methodology- The trial was a randomized parallel group carried out in 30 children aged 3 to 6 years presenting with the clinical features of under-nutrition who were divided into two groups equally. In *Pathadi churna* (group A-trial) and protein powder (control, group B), *Pathadi churna* and protein powder respectively was given in dosage according to age as per Young's formula for 60 days. Results were analyzed according to frequency %, PEM (protein energy malnutrition) gradation shift, changes in assessment parameters, and the level of significance were noted by using Wilcoxon signed rank test and the Student's paired t-test. Results- Significant results were noted in *Daurabalya* (~Fatigue) in both the groups whereas the *Pathadi churna* group showed significant results in the *Agnimandya* (~Lack of appetite & poor digestion), weight, weight for height, BMI, PEM gradation, and the values of hemoglobin, serum proteins & calcium. On comparing both groups, statistically significant differences were seen in *Pathadi churna* than Protein powder. Conclusion- Significant results were seen in *Daurbalya* in both the groups but on comparison more significant effects were noted for all subjective and objective criteria in the *Pathadi churna* group. No ADR was reported in the study. Further large sample studies with standard control would render better evidence in results with justification.

Keywords: Ayurveda interventions, Preschool children, *Pathadi churna,* Protein Powder, Karshya, Undernutrition.

Introduction

In Ayurveda, *Kaumarabhritya* is a branch of science that deals with all elements of children's health from genetics to dietetics (1). *Shosha* means "to dry up" *Rasadi dhatu* also known as *Kshaya* is produced by the vitiation of *Kapha dosha.* In this condition, numerous physiological functions that are constantly performed in the body such as respiration, circulation, digestion, etc. are affected and gradually decline i.e., *Rasadi dhatus* '*Kshaya'. Rasa Dhatu (~Plasma & lymph)* is important in all *Sapta Dhatu* which is responsible for the nourishment of the body (2). *Karshya* is a condition in which a person becomes lean due to the reduction of *Rasa Dhatu* (3). Lean and thin people can be affected by any kind of *Vatavyadhi* (4). *Atikrush* (a very thin person) comes under *Ashtanindita Purusha* (5) for *Chikitsa*. Symptoms of *Karshya* are *Shushkashroni, Udar* and *Greeva (*emaciated buttocks, abdomen and neck) *Dhamanijalasantata* (prominent venous network in the body), *Sthoolaparva* (prominent inter-phalangeal joints), *Pipasa* (thirst) and *Kshudha* (hunger).

According to National Family Health Survey carried out in 2015-16 in India 36% are underweight below the age of 5 years, 38% are stunted and 21% are wasted. In 2017, stunting prevalence globally declined from 32.6% to 22.2% of under 5 years of age group children as per UNICEF data (6). In 2018, 40% were (Severe-14%, Moderate-26%) underweight. Their prevalence was found higher among boys in the Wardha district whereas 34% were suffering from stunting (severe-13%, moderate-21%). Boys were more stunted than girls (boys-40%, girls-28%), 28%-wasting (severe-6%, moderate-22%) (7). Illiteracy, poverty of family and variable food habits of preschool children are the common causative factors of *Karshya* which affect preschool children of present-day also, in fact,

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more aggravated due to changes in diet and lifestyle of the present era (8).

Undernutrition means low weight-for-age, Stunting means low –height–for–age and wasting means low weight–for height (9). Undernutrition may develop due to malnutrition of the mother itself producing low birth weight (infants are undernourished) infants, as well as diseases such as diarrhea, pneumonia and other infections, resulting in more energy use and a reduction of growth. Other important causes of undernutrition are improper breastfeeding, delayed complementary feeding and poor dietary intake. Proteins are the second most abundant substance in the body after water. They are essential for the growth and development of the body; hence control group of protein powder intervention was compared with the trial *Pathadi churna* group having main ingredients as depicted in table no. 1 having 8 parts each except *triphala.*

Table 1: Showing ingredients of *Pathadi churna* with action & other details

Sr.no	Medicine	Pharamcodynamics	Action	Calories/Vitamines
1	*Patha (Cissampelos pareria* Linn., *root,*)	Anti-spasmodic, diuretic.	*Kapha-vatajshula.*	Pesoline, berberine, saponine, cyclomoline
2	*Vella (Embelia ribes* Burn, fruit,	Appetizer, Purifier, Digestive	*Krimighna*	Embelin, volatile oil, resin, tannin, crystembin, crarsitol
3	*Haritaki-Terminalia chebulla* Retz, fruit, 2.5 parts	Laxative, appetizer	*Tridoshghna, krimighna*	Chebulenic acid,18 amino acids, phosphoric, succinic, quinic acids, tannin
4	*Bibhitaki (Terminalia belerica* Roxp, fruit, 2.5 parts	Laxative, appetizer, Haemostatic in nature.	*Krimighna, Pachana,*	Chebulic acids, mannitol, glucose, galactose, fructose, raminose.
5	Amalaki (*Emnelica officinalis* Burn, fruit, 2.5 parts*)*	Anti-spasmodic, Anti-spasmodic.	*Tridoshgna*,	Tanin acid, gallic acid, sugar, albumin, calcium, plenty of Vit. C, and Cellulose.
6	*Ambu (Tagara) (Valaeina wallichi,root,*)	Diuretic, Anti- spasmodic, Anti-bacterial.	*Kapha-Vatashamaka.*	Isovaleric and beta methyl valeric acid, calarene, vit. c, protein(4.63g), Fat(1.17) Cartenoids (132.7gm), calcium(829.9), iron(272gm), zinc(4.80gm), copper(2.69).
7	*Dhataki* (*Woodfordia fruticose* Kurz, flower, *)*	Anti-pyretic, Bloodpurifier, Appetizer	*Tridoshaghna, Varnaropana, Purishastambhana*	Tanin,sugar,galic acid, B sistesterol.
8	*Alla (Dhanyak Coriandrum sativum* Linn*)*	Anti-spasmodic, Haemotasis, Appetizer, Laxative	*Pittashamaka, Kaphaghna Krimighna.*	Coriandol(oil), calcium, iron, phosphorus, and fat.
9	*Visha (Aconitum hetrophyllum)*	The binding agent, anti-emetic,	*Krimighna, Arshoghna, pachana, grahi, Kaphaghna.*	Starch, hetroticine, Bsistosterol, Bcarotine, acticine
10	*Shringi (Pistacia integerrima)*	Binding agent, appetizer,	*Vataghna, Kaphaghna.*	Tanin,(20 to 75 p.c),resin, Bsistesterol, volatile oil, masticardionic acid.
11	Shati (*Hedechyum spicatum* Buch, rhizome*)*	Analgesic,Anti-bacterial,Anti-helminthic, Anti- oxidant	*Kapha-vatashamaka,Ruchikara,*	Hydrocardons, monoterpenes, sesquiterpenes, terpinen,
12	*Vyushna Zinziber officinalis* Roxv, rhizome	Laxative, Digestive	*Tridoshaghna,ruchikara,amapachana*	Zinzerol, Carbohydrate(60-70%),3-6% fatty oil, protein,9%, fiber 3-8%.
13	*Bilva(Aegle marmelos) fruit*	Laxative, Anti-diuretic, hypoglycaemic agent. Anti–emetic agent, binding agent	*Deepna,pachana, krimighna,tridoshaghna*	Protein 2gm, Mineral2gm, fiber3gm, calcium 85gm, phosphorus 50mg, carbohydrate 32gm,
14	*Tirit (Symplocos recemosa* Robx, *Fruit)*	Haemostatis, capillary constrictor,	*Stambana,kaphaghna*	Flavonides, anthocyanin,Tannins, Alkaloids,
15	*Dipya (Carumrox Burghianum, fruit)*	Anti-spasmodic, Anti-convulsive, diuretic, Carminative,	*Krimighna,kaphaghna, pachana*	Crystalline,alkaloid called Ketone,zinc ,iron, sodium, phosphorous, calcium, magnesium.

16	*Hapusa(Sherani)/Hanber Junipercummunis* Linn, fruit	Anti- spasmodic, wormicide,Appetitizer	*Kapha -vatashamaka*	Fatty acids, tannins, flavonoids, resin, copper, calcium, iron, phosphorous, magnesium, vit.c, potassium.
17	*Musta (Cyperrotundus linn mnn*staka, rhizome)	Anti-pyretic,Anti-diuretic, wormicide,	*Tridhoshaghna,grahi,trishna-nigrahana,*	Zizerone, salinese, tannins, salinene.
18	*Amramajja*(*Mangiphera indica, fruit)*	Anti-oxidant,Wormicide,appetitzer	*Kapha-pittashamaka(kernel),vata-pittashamaka(ripe fruit)*	Carbohydrate,(76.14%)crude fiber(0.49%), fat(9.84%) ash(2.43%), crude protein, (5.20%),
19	*Ashvagandha* (*Withania somniphera, root)*	Analgesic, Antioxidant, Diuretic, nutritious, immune-nodulator	*Vataghna, Kaphghna,krimighna, deepana,*	Tannins,Flavonids,calcium,protein, phosphorous,

Pathadi churna with milk has been given to increase weight in children (10). The ingredients and the quantity of Soyavit components are as depicted in table no 2

Table 2: Shows the ingredients of Soyavit protein powder with the quantity of nutrients & other details

Sr.no	Nutrients	Per100gcontains	Perserving10gpowder	%of RDA
1	Niacinamide	50mg	5mg	27.77
2	Vitamin C	50mg	5mg	37.5
3	VitaminB1	4.0mg	0.4mg	28.57
4	VitaminB2	4.0mg	0.4mg	25
5	Vitamin B6	1.0mg	0.1mg	5
6	Vitamin A	2400mcg	240mcg	40
7	Folic acid	800mcg	80mcg	40
8	VitaminB12	3.5mcg	0.35mcg	35
9	Calcium	1500mg	15mg	25
10	Iron	25mg	2.5mg	14.70
11	Zinc	20mg	2mg	16.66
12	Iodine	140mcg	14mcg	

Thus, the present study was aimed at comparing the efficacy of *Pathadi Churna* and Protein Powder in children aged 3 – 6 years who were suffering from *Karshya*.

Methodology

The present study was a randomized parallel group open label single center comparative clinical trial which was approved by the Institutional Ethics committee with Ref. No. DMIMS(DU)/IEC/ Jun-2019/8036.The CTRI number of this trial was CTRI/2020/03/032172(DE).The trial was carried out in 30 children aged 3 to 6 years with general signs and symptoms of undernutrition irrespective of their sex, caste and socio-economic status who were included from the OPD and IPD of a teaching hospital. Subjects suffering from Infectious diseases like Tuberculosis, HIV and any other systemic disorders along with the known case of Hyperthyroidism were excluded from the study. The included children were divided into two groups of 15 each following the internet-generated random number table and were named as Group *Pathadi churna* and Protein Powder. The study was open label and no blinding was done. The total duration of the trial for both groups was for a period of 60 days. The dosage of *Pathadi churna* and Protein Powder (11) were decided as per Young's formula depicted in the dosage table no. 3, same dose, duration and anupan for both the interventions.

Table 3: Drug Dosage of both interventions in children with Karshya for both groups

Age in years	Dosage in grams
3	2.5
4	3
5	3.5
6	4

Pathadi churna and protein powder were advised to take with one cup of milk as *Anupan* for its *brimhan* (anabolic) action as mentioned in *Charka samhita*.

The effect of therapy was assessed on the basis of changes noted in both subjective and objective parameters. Subjective parameters were selected from the context of under-nutrition in Ayurveda classics such as *Agnimandya*, *Twakrukshata*, Daurbalya, tolerance to bear thirst and general weakness of the body which were assessed on the 0^{th}, 15^{th}, 30^{th}, 45^{th}, 60^{th} day and post-treatment 30^{th} day and 60^{th} day of the trial and graded according to severity as 03, 02, 01 and 00 for severe, moderate, mild and absent respectively. On similar days the anthropometrical parameters such as weight, weight for height, body mass index and mid-arm circumference were also assessed. Objective parameters such as CBC, Serum protein and Serum

Calcium were noted in their respective values before (0th day) and after (60th day) of the trial. The obtained results were analyzed on the basis of the above parameters with Wilcoxon signed rank and Student's paired t-test to check the level of significance. P value of < 0.05 was considered significant. The overall effect of the therapy was assessed by improvement in parameters by 25 percentage margins at the end of the trial. As it is a categorical data hence it was assessed by frequency %. Post-treatment follow-up was conducted for a period of 8 weeks.

Observations and Results

In the present study, a total of 33 children got enrolled among them 3 children dropped out due to issues with feasibility and personal problems. A maximum number of subjects 40.9% belonged to the age group of 6 years (running) in group A whereas 33.3% were in group B. In Group A, 33.3% and 9.1 % in Group B were of 3 years age whereas 4 years aged participants % were 9.1 and 13.3 respectively in group A & B. 66% of girl participants were affected by PEM second grade in Group A than 46.67% of boys in Group B. The major diet of the children in both the groups was although mixed type but with lesser consumption due to presence of Agnimandya. In the present study, the maximum number of children belonged to a middle-class family who had closed sanitation and good hygiene, but undernutrition was the major cause due to lack of appetite and poor digestion ability.

Daurbalya was 100% present in both the group subjects in all 30 children and at the end of the trial it was completely cured in both groups. *Twakrukshata* (dryness of the skin) was present in12 80% of children pre-treatment and 20 % post-treatment in both groups A and B while 11 (73.3 %) were relieved during the trial of the study.

Agnimandya was present in 13 children in group A and 14 children in group B during the study while at the end of the trial, 11 children were cured in group A and 9 children were cured in group B. At the end of the study, highly significant results were seen in Group A. All children of both groups showed significant results in *Daurbalya* and *Agnimandya* whereas on comparison it is found that subjects of group A depicted more efficacy as compared to group B, shown in Tables No. 4 & 5.

Table 4: Relief in subjective parameters in Group A

Symptoms	Before Treatment	After Treatme	Relief freque	% Relief
Daurbalya	15(100%)	0(0%)	15	100%
Twakrukshata	12 (80%)	11(73.34	1(6.66	6.66%
Agnimandya(Lack	13(86.67%	2	11(73.3	73.34%

Table 5: Relief in subjective parameters in Group B

Symptoms	Before Treatment	After Treatm	Relief Score	% Relief
Daurbalya	15(100%)	0(0%)	15	100%
Twakrukshata	12 (80%)	11(73.3	1(6.66%	6.66%
Agnimandya (Lack	14(93.33%	9 (60	5(33.33	33.33%

In Tables No 4 and 5, the relief score was calculated as per the formula and later relief % was drawn.

Findings of Anthropometrical parameters are given below

The significant results of the trial drug were shown in Anthropometrical parameters in group A except in the parameter of height.

A comparison of weight in the two groups showed that group A was more significant than group B. The comparison of height in the two groups data was insignificant. Effect of BMI in both the groups on the 15th day, 30th, 45th, and 60th day of study during treatment and post treatment follow up was highly significant in group A than in group B. PEM grading data was statistically significant in group A than in group B as shown in Table no. 6.

Table 6: Showing the Shifting distribution of patients in both groups as per PEM grade II to I

	PEM II		PEM I		
	Before t/t	After t/t	Before t/t	After t/t	z-value
Group A	15(100%)	5 (33.33 %)	0 (0%)	10 (66.67%)	3.8731, Significant
Group B	15(100%)	7 (46.67 %)	0 (0%)	8 (53.33%)	3.3038, Significant

Z score>1.96 is considered a Significant

Z-test for the difference between two proportions

Table No. 4 shows that before treatment 15 (100%) patients were in grade 2 from each groups A and B. and after treatment, group A was more significant than group B. Table No.7 shows the comparative results of both the groups on hematological parameters which were significant in the single group but on comparison the result was insignificant in both parameters.

Table 7: Showing Comparison of Hb% in two groups.

	Before t/t	After t/t	Comparison between before and after t/t(Student's paired t-test) t-value, p-value
Group A	11.33±1.37	11.42±1.25	2.18,p-value=0.046,S*
Group B	11.65±0.64	11.83±0.69	1.00,p-value=0.33,NS**
t-value	0.81	1.11	*S-significant
p-value	0.42, NS	0.27, NS	**NS-non-significant

Table No. 7 shows that the p-value of Hb% before and after treatment in group A was 0.33 and 0.046 in group B. Data was statistically significant in group A than in group B.

Table 8: Showing Comparison of Sr. Protein in two groups

	Before t/t	After t/t	Comparison between before and after t/t(Student's paired t-test)t-value, p-value
Group A	7.08±0.58	7.31±0.60	3.83, p-value=0.002, S
Group B	7.38±0.25	7.45±0.19	1.79, p-value=0.09, NS
Comparison between Group A and Group B (Student's unpaired t-test)			
t-value	1.81	0.85	
p-value	0.08, NS	0.40, NS	

Table No. 8 shows that the mean value of protein was 7.08 in group A before treatment and 7.38 in group B. After treatment, it was increased by 7.31 and 7.45 in both the group respectively. It showed highly significant results in group A.

Table 9: Comparison of Sr. Calcium in two groups

	Before t/t	After t/t	Comparison between before and after t/t (Student's paired t-test) t-value, p-value
Group A	8.81±0.58	9.10±0.61	3.80, p-value=0.002, S
Group B	9.20±0.42	9.26±0.39	1.41, p-value=0.17, NS
Comparison between Group A and Group B (Student's unpaired t-test)			
t-value	2.07	0.79	
p-value	0.048, S	0.43, NS	

Table No. 9 shows the mean value of calcium was 8.81 before treatment in group A and 9.20 in group B. After treatment, it was increased by 9.10 and 9.26 in both groups respectively. It showed highly significant results in group A. On comparison between group A and group B, the t value was 2.07 before treatment and after treatment, the t value was 0.79.

Table 10: Comparison of group-wise and overall percentage improvement in patients

Assessment	Group A	Group B	Total
Complete Remission	0(0%)	0(0%)	0(0%)
Markedly Improvement (>75%)	2(13.33%)	1(6.67%)	3(10%)
Moderate Improvement (51-75%)	10(66.67%)	9(60%)	19(63.33%)
Mild Improvement (25-50%)	3(20%)	5(33.33%)	8(26.67%)
Unchanged (<25%)	0(0%)	0(0%)	0(0%)
Total	15(100%)	15(100%)	30(100%)

Table No. 10 shows a marked improvement in group A (13.33%) than in group B (6.67%) and a total of 10%. Moderate improvement of 66.67% was seen in group A and 60 % in group B whereas 20% mild improvement in group A and 33.33% in group B and a total of 26.67%. This is categorized data derived from frequency and &% hence mean, SD cannot be calculated.

Results

Hence, it can be concluded that *Pathadi Churna* can be effectively used in children with *Karshya* (Undernutrition) as it showed maximum improvement (66.67%) when compared with 60% to Soyavit Protein Powder alone.

Discussion

According to Ayurveda, *Vata* is the main causative factor to induce malnutrition in children. PEM can be correlated with *Karshya* (~emaciation) based on similar clinical features. If *Mandagni* (lack of appetite) is present, it leads to *aam* (undigested toxic element) and *srotodushti* (blockage in microchannels) (12). There are many causes like improper nutrition, un-hygiene, recurrent health problems with no quality care, etc. (13). The ideal treatment is to stimulate appetite, increase microcirculation, to remove deficiency by supplementing nutrition, anti-helminths, and immunomodulators (14). Analytical tests revealed that the trial medicine had no microbiological content and a quality control test revealed that *Pathadi churna* had a pH of neutral and no contamination. A total of 30 children enrolled randomly in the trial received *Pathadi churna* and *Soyavita* Protein Powder as per the groups. Overall, the maximum children in the study were girls from middle-class families and in a group of 3-6 years. In this study, the main etiological factors, irrational consumption of food like more packed food and insufficient quantity of intake were prominent (15) causes of PEM.

Probable mode of action of the drug

The probable mode of action of *Pathadi churn* and Soyavit Protein Powder can be interpreted by the pharmacokinetics and pharmacodynamics of the ingredients. Characteristics of grossly all ingredients such as *Rasa* and *Vipaka-Madhura, Guna-Snigdha, Guru, Virya-Shita, Karma- Vatashamana, and Brimhana* were the prime factors which might have influenced the action of the formulation (16).

Some drugs in trial drug- *Pathadi churn* are having the properties of *Agni deepana, Brimhana, and Vatashamana* which enhanced the action of *Pachakagni* and *Dhatwagni* improves digestion and absorption of nutrients. Correction in *Dhatu poshana* helped to pacify *Karshya Lakshana*, thus increase in the nutritional status and shifting of PEM gradation from second to first and first to 0 malnutrition grade achieved in this study. As per the IAP-Indian Academy of Pediatrics there are four grades of PEM in children. When observed weight is more than 80% of ideal weight then there is no malnutrition but when it is in between 70-80 %, it is grade 1, similarly, when it is 60-70 %-2nd; 50-60-3rd grade and less than 50%, it is grade 4 to indicate the severity. Although protein is of utmost requirement for body building but control drug Soyavit has no ingredients to work upon appetite and digestion.

Pathadi churna has good nutritional potential as well as an appetite booster. These features of the trial medication, when provided internally have a major role in *vatashaman* as stated in *Ayurvedic* classics (17,18). Both the medications have established significant efficacy in *daurabalya* (100%) but group A children receiving Pathadi churna have received excellent efficacy in *agnimandya* (66.67%) and proved the game changer resulting in the shifting of PEM grade II to I. In a previous study, *Ashwagandha ghrita* was used and found effective for weight gain in children with *Karshya* (underweight) (19). The nutrition supplement concept is supported by other similar research work that is directly related to less intake of nutritious diet therefore medicines has given good subjective as well as objective relief (20,21). In one previous study it was concluded that *Vidaryadi ghrita* can be used effectively for weight gain in *Karshya* as there is more improvement as compared with the diet programme alone (22). A highly significant result was found in anthropometry in both groups. In Group A (*Vidarikandadi vati*) increased effect was observed only during the treatment when therapy stopped, the increment becomes slow but it is steady in the *Basti* group (*Ksheerbala taila* basti). In hematological parameters also both groups showed significant results, but it is insignificant statistically (23). The previous study shows that the selected drug KP (*Khajurapaka)* helps to improve the sign and symptoms of *Mamsakshaya*. (24). All these studies showed efficacy on Agni then only brimhan effect is visible. This study also proved that *Pathadi churna* administered in children with *Karshya* showed *Agnideepana* and *brimhana* effect due to the synergistic action of trial drug ingredients. (25, 26). The limitation of this study includes small sample size and limited laboratory investigations. It is recommendable that similar work needed to be done on a larger sample size at multi centers with necessary laboratory investigations such as lipid profile, blood sugar, amino acids, transferritin and IgG-IgM.

Conclusion

Karshya is a disorder in which *Dhatu Kshaya* is the main pathology and it can be linked to undernutrition in the modern medical system due to clinical similarities. In the nutshell, subjective and objective parameters showed a good response in *Pathadi churna* than Soyavita Protein Powder mainly due to an increase in appetite (Agnideepti) which was less noticed in the protein powder group. *Pathadi churna* did not have any palatable issues in children but convincing was needed. Both the drugs were well tolerated by the children with anabolic effect and they had a major role in relieving all manifested clinical features within the short duration of 60 days. So, it can be suggested in routine pediatric practice for weight gain in children with *Karshya* (Undernutrition) as it showed maximum improvement (66.67%) when compared with Soyavit Protein Powder alone by 60 %.

Conflict of interest: Nil

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