**Clinical Research** 

# Role of *Kasahara Dashemani Vati* in *Kasa* and *Vyadhikshamatva* in children with special reference to recurrent respiratory tract infections



Access this article online Website: www.ayujournal.org

#### Nayan Kumar Subrahmanya, Kalpana Shanthibhai Patel<sup>1</sup>, Virendra Kumar Kori<sup>2</sup>, Rajagopala Shrikrishna<sup>2</sup>

Assistant Professor, Department of Kaumarabhritya, SDM College of Ayurveda and Hospital, Hassan, Karnataka, Associate professor and Head<sup>1</sup>, Assistant Professor<sup>2</sup>, Department of Kaumarabhritya, Institute for Post Graduate Teaching and Research in Ayurveda, Gujarat Ayurved university, Jamnagar, Gujarat, India.

#### Abstract

The present single-centered randomized control trial (RCT) was carried out with the prime aim of assessing the effect of Kasahara Dashemani Vati (trial drug) on Kasa and Vyadhikshamatva in the children suffering from recurrent respiratory tract infections and comparing it with the efficacy of Indukanta Vati. The clinical trial included 40 patients belonging to age group of 3-12 years. The drugs were administered in a daily dose fixed as per "Clark's Rule" along with honey for duration of 60 days. The effect of treatment on the signs and symptoms of Kasa was assessed on the 15th day, whereas the effect on Vyadhikshamatva was assessed on the 60th day. The patients were under follow-up for a period of 60 days after completing the treatment course for evaluation of any recurrence. Effect of the therapy on the individual signs and symptoms of Kasa, laboratory parameters, immunoglobulin (lg) biomarkers, status of Atura Bala, and prevention of recurrence during follow-up period were the parameters used to assess the overall effect of therapy. The observed data were subjected to appropriate statistical analysis for testing the statistical significance. Kasahara Dashemani provided relief in all symptoms of Kasa irrespective of Doshic involvement and on the parameters of Atura Bala. All the changes were statistically highly significant. The control group also showed similar effects which were statistically highly significant. The trial group was found to have a direct influence on serum lg status. No patient has reported any adverse drug reactions during the treatment and follow-up periods.

Key words: Immunoglobulin, Indukanta Vati, Kasahara Dashemani Vati, Recurrent respiratory tract infection, Vyadhikshamatva

# Introduction

Respiratory system is in continuous contact with the external environment since birth until one's lifetime, so it is most vulnerable to infections and considered as the prime victim of hyper sensitization in most of the circumstances.<sup>[1]</sup> Thus respiratory tract infections (RTI) account for more than 50% of patients attending the pediatric OPD in developing and even developed countries worldwide.<sup>[2,3]</sup> Kasa is a disease explained in Ayurveda which involves most of the presentations of a respiratory tract disease. In the pathogenesis of disease Kasa, vitiated Kapha obstructs the free flow of Prana Vata in Kantha

Address for correspondence: Dr. S. Nayan Kumar, Assistant Professor, Department of Kaumarabhritya, SDM College of Ayurveda and Hospital, Hassan, Karnataka, India. E-mail: nayanpanaje@yahoo.co.in and Uras.<sup>[4]</sup> Since Kapha is the main culprit in production of Kasa and Kapha is the dominating Dosha in Balyavastha (during childhood), the incidence is more in this age group. Pediatric age group is more vulnerable because of anatomical and physiological peculiarities (hypertrophied lymphoid tissues,<sup>[5]</sup> mucous hyper secretion,<sup>[6]</sup> peculiarities of Eustachian tube,<sup>[7]</sup> etc.), immunological considerations<sup>[8]</sup> (first exposure, immature immunological defenses, etc.), and social factors (attending school,<sup>[4]</sup> improper food and eating habits,<sup>[9]</sup> etc.). Recurrent cough is the common manifestation of recurrent respiratory tract infections (RRTI) which is more akin to the disease Kasa delineated in Ayurvedic classics.

Early intervention is necessary in case of *Kasa* as it is a potential *Nidanarthakara Vyadhi* (disease having tendency to produce secondary diseases) to produce *Kshaya*<sup>[10]</sup> (a disease characterized with severe emaciation). It is noted that children suffering from recurrent RTI exhibit significantly hampered growth and development (including intellectual and social up-gradation).<sup>[11]</sup>

In above condition of recurrent *Kasa*, the treatment should fulfill duel targets; one which subsides the disease *Kasa* and the other which promotes the immune system. Ayurveda has many drugs that act on complaints of respiratory system and simultaneously act as immunomodulators as well. *Kasahara Dashemani*<sup>[12]</sup> is a group of 10 herbs where in half are acting on the presenting complaint of *Kasa* to subside it and rest are proven immune-modulators for preventing the recurrence, thus fulfilling the above objectives. It is also accountable to note that these drugs have the capability to subside all the three types of *Doshic* entities. The control drug *Indukanta Vati*<sup>[13]</sup> is frequently used in the southern part of the country in a broad spectrum of diseases, especially in RRTIs; its immunomodulatory action in children has been proved by a number of previous studies.

The present study was carried out with the prime aim of assessing the effect of trial formulation *Kasahara Dashemani Vati* on *Kasa* and *Vyadhikshamatva Shakti* in children against *Indukanta Vati* as the control.

This clinical trial has been cleared by Institutional Ethics Committee Vide Ref-PGT/7-A/Ethics/2010-2011/1858/32 dated 01/09/2010 and the trial has been registered in Clinical Trial Registry of India (CTRI), ref. no. CTRI/2011/10/002062 [Registered on: 13/10/2011].

# **Materials and Methods**

Forty patients fulfilling the inclusion criteria were recruited from the *Kaumarabhritya* OPD of the institute. Informed consent of the parent/guardian has been taken prior to the inclusion of the patient in the trial. The trial duration was from 10/2010-08/2011.

#### **Inclusion criteria**

Patients of either sex belonging to age group of 3-12 years presenting with classical signs and symptoms of *Kasa* with at least one episode a month for a minimum duration of 6 months were included in the trial.

#### **Exclusion criteria**

Patients with bronchial asthma, tuberculosis, severe lower RTI (pneumonia, emphysema, bronchiectasis, etc.), or associated with other systemic illnesses were not included in the trial.

#### Grouping and design

Recruited patients were allotted in the trial by randomized allocation method. In the present study, the powdered tablets were administered in three divided doses given after food along with honey (quantity sufficient) for duration of 60 days. The daily dose was calculated based on the body weight (Clark's Rule), with adult dose as 12 g<sup>[14]</sup> per day. The effect of treatment on the signs and symptoms of *Kasa* was assessed on the 15<sup>th</sup> day after starting the treatment, whereas the effect on *Vyadhikshamatva Shakti* was assessed on the 60<sup>th</sup> day (after completion of the treatment). All the patients were under regular follow-up for examination of any recurrence in the signs and symptoms of *Kasa* for a period of 60 days after completing the treatment course.

## Laboratory investigations

Routine blood, urine, and stool examinations were carried out before treatment to rule out any major associated diseases and after treatment to screen for significant hematological or biochemical changes. Total leukocyte counts (TLC) and absolute eosinophil count (AEC) were taken as the indicators of infection and allergy respectively. Serum Ig-E and IgG were estimated as immunological bio-markers for evaluating the drug action on humoral immunity.

#### Assessment criteria

Effect of the therapy on the individual signs and symptoms of *Kasa*, routine laboratory parameters, immunoglobulin (Ig) biomarkers IgG and IgE, status of *Bala* (*Agni*, *Deha*, and *Satva*), and prevention of recurrence in the signs and symptoms of *Kasa* during the follow-up period were the parameters used to assess the overall effect of therapy on *Kasa* and *Vyadhikshamatva*. The overall effect of the therapy was derived by a specially designed scoring system by considering both subjective and objective parameters of assessment.

#### **Statistical analysis**

The individual and overall effect of therapy of each group (within group) was tested for statistical significance by using paired Student "*t*"-test, whereas the comparative effect of trial and control groups (between two groups) was tested by using unpaired Student "*t*" test. Wilcoxon Signed Rank Test was done wherever Student "*t*" test was not possible. The results were interpreted at P < 0.05, P < 0.01, and P < 0.001 significance levels. The obtained results were interpreted as: Insignificant P > 0.05, significant P < 0.05, highly significant P < 0.001.

# Results

# Trial drug

Kasahara Dashemani Vati on Vataja symptoms provided 65% relief in Shushka Kasa, 73% relief in Shirashoola, 75% relief in Hritshoola and 53% relief in Daurbalya. Provided 100% relief on Jwara and 75% of relief on Peeta Nishtheevana which are Pittaja symptoms. On Kaphaja symptoms it provided 64% relief in Swetakapha, 57% in Mandagni, 79% in Peenasa, 59% in Aruchi, and 100% relief in Vamana. All the changes were statistically highly significant with P < 0.001. The formulation also showed statistically highly significant relief in the duration of each bout, daily frequency of bouts, and the nature of sputum parameters [Table 1]. On Atura Bala the trial drug provided 45% improvement in the Agnibala, 50% improvement in the Dehabala, 6.5% in the Sharira Upachaya, and 36% improvement in the Satvabala. All the above changes were statistically highly significant [Table 2].

On the laboratory parameters, the trial drug showed a decrease of 2.67% in TLC, a decrease of 5.39% in total polymorphs, a decrease of 3.21% in AEC, and a decrease of 32.42% in the erythrocyte sedimentation rate (ESR). It is also observed that there was an increase of 5.27% in absolute lymphocyte count (ALC). All the changes were statistically insignificant. There was increase in serum albumin, whereas globulin and total proteins showed a decrement. The changes were statistically insignificant except in globulin which was statistically

(Kasahara Dashemani Vati treated)										
Features	Ν	вт	AT	% of relief	±SE	Т	Р			
Shushka Kasa	06	2.83	1.00	64.71	0.16	11.05	< 0.001			
Shirashoola	05	2.20	0.60	72.73	0.21	6.41	< 0.001			
Hrit Shoola	07	2.29	0.57	75.00	0.17	10.04	< 0.001			
Daurbalya	07	2.14	1.00	53.33	0.22	4.66	< 0.001			
Peetanishtheeva	08	2.50	0.63	75.00	0.28	6.79	< 0.001			
Jwara	12	1.75	0.00	100	0.13	14	< 0.001			
Swetakapha	06	2.33	0.83	64.29	0.20	7.06	< 0.001			
Mandagni	07	2.00	0.86	57.14	0.13	8.64	< 0.001			
Aruchi	13	2.23	0.92	58.62	0.13	10.18	< 0.001			
Vamana®	09	2.00	0.00	100.00	0.00	-	<0.01			
Peenasa	14	1.00	0.21	78.57	0.10	8.33	< 0.001			
Duration of each bout	20	01.30	00.29	77.88	0.13	7.78	<0.001			
No. of bouts	20	18.20	04.1	77.47	1.21	11.62	< 0.001			
Sleep disturbance	11	01.55	00.27	82.35	0.14	09.04	< 0.001			
Nature of sputum	20	01.95	00.65	66.67	0.16	07.93	<0.001			
Sleep disturbance Nature of sputum @Wilcoxon signed rank te	11 20	01.55 01.95 as done a	00.27 00.65	82.35 66.67 /as not pos	0.14 0.16 sible.A	09.04 07.93 T:After tr	<0.00 <sup>-</sup> <0.00 <sup>-</sup>			

Table 1: Effect on symptoms of Kasa in group A

BT: Before treatment, SE: Standard error

Table 2: Effect on Aturabala in Group A (KD Vati         treated)										
Features	Ν	BT	ΑΤ	% of relief	±SE	Т	Ρ			
Agnibala	20	08.55	04.70	45.03	0.34	11.16	<0.001			
Dehabala	20	04.80	02.40	50.00	0.13	18.09	<0.001			
Sharira upachaya/Wt	20	19.90	21.19	6.48	0.11	10.93	<0.001			
Satvabala	20	07.45	04.80	35.57	0.23	11.06	<0.001			
AT: After treatment	, BT: B	efore trea	tment, SE:	Standard e	error					

significant. Both the biomarkers IgG and IgE showed a decrease of 6.66% and 37.85% respectively. The changes were statistically not significant [Table 3]. The overall effect of treatment in Group A was 53.82%, which was statistically highly significant.

# **Control drug**

On Vataja symptoms, Indukanta Vati provided a relief of 56% in Shushka Kasa, 60% relief in Shrashoola, 76.47% in Hritshoola, and 67% relief in Daurbalya. On Pittaja symptoms, it showed 64% relief in Peetanishtheevana and 100% relief in Jwara. On Kaphaja symptoms the drug showed 74% relief in Shwetakapha, 73% on Mandagni, 67% relief in Aruchi, 100% relief in Vamana, and 92% relief in Peenasa. The results were statistically very highly significant except in Shirashoola and Swarabheda where it was statistically insignificant. It was also observed that the drug provided statistically highly significant relief in duration of each bout, daily frequency of bouts and the nature of sputum parameters [Table 4]. On Aturabala, the control drug provided 39% improvement in Agnibala, 47% improvement in Dehabala 6.4% improvement in Sharira Upachaya, and 29% improvement in Satvabala. The changes were statistically highly significant [Table 5].

On laboratory parameters, Indukanta Vati group showed a decrease of 13.22% in TLC and a decrease of 11.51% in polymorphs, 2.7% in AEC, 2.21% in ALC, and a decrease of 35.84% in ESR. The changes were statistically insignificant except in neutrophil which was significant. There was 2.38% increase in serum albumin, whereas globulin and total proteins showed a decrement of 7.25% and 1.67% respectively. The changes were statistically insignificant except in globulin which was highly significant. Both the biomarkers IgG and IgE showed mild decrease. The changes were statistically insignificant [Table 6]. The overall effect of treatment in Group B was 52.06%, which was statistically highly significant. When the individualized overall effect of therapy were considered, 65% of patients in Group A and 60% of patients in Group B reached moderate improvement zone (50-75% improvement), 30% of Group A and 35% of Group B reached mild improvement zone (25-50% improvement) and 5% of the patients in each group showed no improvement. On follow-up, 65% of the patients from Group A and 60% of patients from Group B had no recurrence of the symptoms. 30% of the patients from Group A and 40% of patients from Group B had recurrence but with lesser frequency and intensity. 5% of the patients from Group A had recurrence with same frequency but lesser intensity.

No adverse drug reactions have been reported by any of the patients during the treatment or follow-up periods.

# Discussion

On clinical symptoms of Kasa, Kasahara Dashemani Vati provided relief in all the cardinal and associated symptoms of Kasa irrespective of their Doshic presentations. All the changes were statistically highly significant. Even though it is effective in all types of Kasa; there is a slope in the curve of efficacy from Vata toward Kapha. The control drug, Indukanta Vati also showed improvement in all the clinical symptoms of Kasa. The changes were statistically highly significant. When compared, among Vataja symptoms, the trial group showed better results on Shushka Kasa and Shirashoola, whereas control drug was better on Daurbalya. Shushka Kasa is the main diagnostic feature of Vataja Kasa, it can be said as trial group has better effect on Vata predominant Kasa. In modern perspective, Shushka Kasa and Shirahshoola (Vataja Shirahshoola) can be co-related to allergic conditions. Daurbalya is more common in infectious conditions rather than in allergy. Trial group was found to be more effective on Pittaja Kasa, because of the ingredient drugs such as Draksha, Amalaki, Duralabha, and Bhumyamalaki which provide an additional Pittahara property. On all symptoms of Kaphaja Kasa control drug showed far better results than the trial drug with a statistically significant better effect on Shwetakapha. This is at par with the additional Kaphahara property of Indukanta Vati because of the presence of Panchakola [Table 7].

#### Parameters of Bala

Even though both the trial and control drugs showed marked improvement on the parameters of Bala (Agnibala, Dehabala, Satvabala, and Shareeropachaya) which was statistically highly significant; the trial drug showed marginally better results which may be because of additional Rasayana effect of Kasahara Dashemani [Table 7].

Table 3: Effect on lal	able 3: Effect on laboratory parameters in Group A (KD <i>Vati</i> treated)											
Parameters	N	BT	AT	% change	±SE	Т	Р					
Total WBC	20	8425	8200	02.67↓	425.99	0.53	>0.05					
Neutrophil (%)	20	52.85	50.00	05.39↓	2.81	1.01	>0.05					
AEC	20	489.65	473.95	03.21↓	113.99	0.14	>0.05					
ALC	20	3164.95	3331.80	05.27↑	213.06	0.78	>0.05					
ESR (mm/1 <sup>st</sup> h)	20	21.90	14.80	32.42↓	3.76	1.89	>0.05					
Albumin (g/dL)	20	4.01	4.02	0.37↑	0.04	0.36	>0.05					
Globulin (g/dL)	20	3.15	2.90	8.10↓	0.11	2.37	<0.05					
Total protein (g/dL)	20	7.16	6.92	3.35↓	0.12	2.03	>0.05					
lgG (mg/dL)	20	1017.70	949.90	6.66↓	45.94	1.48	>0.05					
IgE (IU/mL)	20	418.92	260.34	37.85↓	96.99	1.64	>0.05					

↑: Increase, ↓: Decrease, AT: After treatment, BT: Before treatment, SE: Standard error, AEC: Absolute eosinophil count, ALC: Absolute lymphocyte count, WBC: White blood corpuscles, ESR: Erythrosite Sedimentation Rate, IgG: Immunoglobulin G, IgE: Immunoglobulin E, SE: Standard error

able 4: Effect on symptoms of Kasa in Group B (Indukanta Vati treated)										
Features	N	вт	AT	% of relief	±SE	Т	Р			
Shushka Kasa	04	2.25	1.00	55.56	0.25	5.00	<0.001			
Shirashoola®	03	1.67	0.67	60.00	0.00	-	>0.05			
Hrit Shoola	09	1.89	0.44	76.47	0.18	8.22	<0.001			
Daurbalya	03	2.00	0.67	66.67	0.33	4.00	<0.001			
Peetanishtheeva	09	2.78	1.00	64.00	0.15	12.09	<0.001			
Jwara	08	1.88	0.00	100.00	0.13	15.00	<0.001			
Swetakapha	08	2.88	0.75	73.91	0.13	17.00	<0.001			
Mandagni®	11	1.36	0.36	73.33	0.00	-	<0.001			
Aruchi	12	2.50	0.83	66.67	0.14	11.73	<0.001			
Vamana	07	2.14	0.00	100.00	0.14	15.00	<0.001			
Peenasa	13	1.00	0.08	92.31	0.08	12.00	<0.001			
Duration of each bout	20	1.18	0.29	75.74	0.12	7.45	<0.001			
No. of bouts	20	17.50	4.70	73.14	1.37	9.33	<0.001			
Sleep disturbance	12	1.08	0.08	92.31			<0.001			
Nature of sputum	20	2.45	0.75	69.39	0.13	13.31	<0.001			

<sup>@</sup>Wilcoxon signed rank test was done as t test was not possible.AT:After treatment, BT: Before treatment, SE: Standard error

# Table 5: Effect on Aturabala in Group B (IndukantaVati treated)

Features	Ν	BT	AT	% of relief	±SE	Т	Р
Agnibala	20	07.05	04.30	39.01	0.23	12.06	< 0.001
Dehabala	20	04.30	02.30	46.51	0.16	12.33	<0.001
Sharira upachaya/Wt	20	21.64	23.03	6.42	0.15	9.25	<0.001
Satvabala	20	06.30	04.50	28.57	0.14	13.08	<0.001
AT: After treatment		oforo troo	tmont SE.	Standard a	rror		

AT: After treatment, BT: Before treatment, SE: Standard error

## Laboratory parameters

Control drug showed better results in decreasing TLC, polymorphs, and ESR; indicating better effect in infectious conditions. The trial group there was moderate decrease in AEC which shows decrease in the magnitude of allergy so it may be inferred that it is more effective in allergic conditions. 5.27% of increase in ALC in the trial group suggests an increased lymphocytic recruitment, when it is associated with decreased ESR (rules out the chronic infection/inflammation).

The possible explanation is the increased cell-mediated immunity [Table 8].

#### Serum proteins and biomarkers

Trial drug showed a marked decrease in IgG and IgE. Decrease in IgG within normal limits (highly above the cut off mark of < 200 mg/dL to consider the person as immune compromised) suggests the subsidence of infection as there is lesser requirement of IgG after subsidence of infection. There was a marked decrease noted in the serum IgE levels in the trial group which indicates a definite role of the drug against allergy phenomenon. On serum proteins, the drug showed a statistically significant decrease in the serum globulins which may be because of decrease in various Ig levels (mainly IgE and IgG). The control drug had minimum effect on the Ig parameters. On serum proteins, the control drug also showed a statistically significant decrease in the serum globulins, this can also be attributed to a decrease in various Ig levels. On the contrary, there was marginal increase in serum albumin levels in the control group which may be the indication of improved nourishment and metabolic status. From the above data, it may be inferred that the trial drug probably reached

Table 6: Effect on laboratory parameters in Group B (IK <i>Vati</i> treated)											
Parameters	N	BT	AT	% of relief	±SE	Т	Р				
Total WBC	20	8395	7285	13.22↓	285.15	3.89	<0.001				
Neutrophil (%)	20	50.40	44.60	11.51↓	2.36	2.45	<0.05				
AEC	20	322.80	314.10	2.70↓	36.70	0.24	>0.05				
ALC	20	3585.45	3506.25	2.21↓	169.52	0.47	>0.05				
ESR (mm/1 <sup>st</sup> h)	20	17.30	11.10	35.84↓	3.51	1.77	>0.05				
Albumin (g/dL)	20	4.00	4.09	2.38↑	0.06	1.73	>0.05				
Globulin (g/dL)	20	2.90	2.69	7.25↓	0.05	4.32	<0.001				
Total protein (g/dL)	20	6.89	6.78	1.67↓	0.09	1.31	>0.05				
IgG (mg/dL)	20	916.15	897.00	2.09↓	36.55	0.52	>0.05				
IgE (IU/mL)	20	181.77	179.70	1.14↓	50.20	0.04	>0.05				

1: Increase,  $\downarrow$ : Decrease, AEC: Absolute eosinophil count, ALC: Absolute lymphocyte count, WBC: White blood corpuscles, ESR: Erythrosite Sedimentation Rate, IgG: Immunoglobulin G, IgE: Immunoglobulin E, AT: After treatment, BT: Before treatment, SE: Standard error

Table 7: Comparative effect on signs and symptoms
of Kasa and Aturabala in Group A and Group B

Features	df	% of relief		Mean	t	Р
		Group	Group	difference		
		Α	В			
Shushka Kasa	08	64.71	56.56	0.58	2.03	>0.05
Shirashoola	06	72.73	40.00	0.60	1.13	>0.05
Daurbalya	8	53.33	66.67	0.19	0.42	>0.05
Peetanishtheeva	15	75.00	64.00	0.10	0.31	>0.05
Swetakapha	12	64.29	73.91	0.63	2.60	< 0.05
Mandagni	16	57.14	73.33	0.14	1.28	>0.05
Aruchi	23	58.62	66.67	0.36	1.85	>0.05
Vamana	14	100.00	100.00	0.14	1.15	>0.05
Peenasa	25	78.57	92.31	0.14	0.99	>0.05
Agnibala	38	45.03	39.01	1.10	2.67	< 0.05
Dehabala	38	50.00	46.51	0.40	1.71	>0.05
Sharira	38	6.48	6.42	0.10	0.52	>0.05
<i>Upachaya/</i> Wt						
Satvabala	38	35.57	28.57	0.85	2.94	>0.05

 Table 8: Comparative effect on laboratory parameters

 in Group A and B

Features	df	% of c	hange	Mean	t	Р
		Group A	Group B	difference		
Total WBC	38	02.67↓	13.22↓	885.00	1.726	>0.05
Neutrophil (%)	38	05.39↓	11.51↓	02.95	0.80	>0.05
ESR (mm/1 <sup>st</sup> h)	38	32.42↓	35.84↓	00.90	0.18	>0.05
AEC	38	03.21↓	02.56↓	07.00	0.06	>0.05
ALC	38	05.27↑	02.21↓	246.05	0.90	>0.05
IgG (mg/dL)	38	06.66↓	02.09↓	48.65	0.83	>0.05
IgE (IU/mL)	38	37.85↓	03.45↓	156.51	1.43	>0.05
Total protein (g/dL)	38	03.35↓	01.67↓	00.13	0.85	>0.05
Globulin (g/dL)	38	08.10↓	07.25↓	00.05	0.38	>0.05
Albumin (g/dL)	38	00.37↑	02.38↑	80.00	1.16	>0.05

↑: Increase, ↓: Decrease, AEC: Absolute eosinophil count, ALC: Absolute lymphocyte count, WBC: White blood corpuscles, ESR: Erythrosite Sedimentation Rate, IgG: Immunoglobulin G, IgE: Immunoglobulin E, AT: After treatment, BT: Before treatment, SE: Standard error

up to Ig's (humoral immunity) stratum of the immune system to exhibit its dynamics. Whereas the control drug had minimum action on these humoral parameters, it might thus be influencing the immune system through its action on innate and/or cell-mediated immunity or through normalizing the digestion and metabolism [Table 8].

## Overall effect of therapy and follow-up findings

There was 54% of relief in the overall condition of recurrent *Kasa/*RRTI found in Group A and it was 52% in Group B. By considering the above data, it can be inferred that the trial drug is marginally more effective in treating the condition of *Kasa/*RRTI, even though the superiority was statistically insignificant. When the individualized overall effect of therapy was considered, both the formulations showed similar response with a majority of the patients reaching up to the moderate improvement zone followed by those in mild improvement zone. Both the trial and control drugs were almost equally effective in preventing the recurrence of the disease *Kasa*.

In the present disease condition, till date, there is no definite known cure.<sup>[15]</sup> So any sort of improvement in the overall condition is fairly acceptable. The improvement to an extent of around 50% in present study is highly promising and can be studied further.

## Probable mode of drug action

The trial drug Kasahara Dashemani Vati consists of 10 herbs with multi-dimensional properties. The drugs which directly act on the disease Kasa (Kantakari, Pippali, Shringi, Sweta Punarnava/Vrishchira) act by Kapha Vatahara property. The Teekshna drugs such as Kantakari, Pippali, Shringi act locally at the site of Kantha and cause Vilavana of obstructed Kapha. Thus, immediately after removal of Sroto Avarodha caused by Kapha, the Vatahara drugs such as Haritaki cause Vatanulomana and pacify Vimargaga Kupita Vata caused due to Avarana. The drugs with Vatapittahara (Duralabha, Draksha) and Kaphapittahara (Bhumyamalaki) properties come into action when there is association of Pitta. The drugs such as Haritaki, Shringi etc., with Kashaya Rasa have local Kaphahara action on the mucosa. This process explains the symptomatic relief from Kasa. In the later phase, the drugs like Pippali, Haritaki, Sweta Punarnava, and Kantakari do action of Pachana followed by Deepana and Anulomana. This process sets right the digestion, assimilation, and metabolism. Further the drugs such as Amalaki, Punarnava, Haritaki, Draksha, and Pippali nourish the body with their Rasayana effect. These drugs improve Dhatusara and Ojas and thus increase the Vyadhikshamatva.

In modern perspective, the antitussive action of both the drugs is purely through interfering with peripheral mechanisms of the cough reflex. The pungent principles present in both the formulations act as potent antitussives,<sup>[16]</sup> probably by blocking the vagal sensory afferents by counter-irritant and local anesthetic mechanism.[17,18] Piperine, one of the principle components present in both the formulations has recorded its role in modulating the membrane permeability<sup>[19]</sup> which may permit potassium ion influx and have a role on the ion gated mechanism of the mucosal C-type vagal receptors and may up-regulate the cough threshold.<sup>[20]</sup> When administered along with honey, additional demulcent and mucokinetic actions further enhance the antitussive action. Tamalaki (Bhumyamalaki), Kantakari, Shringi, and Madhu have systemic antiviral and antimicrobial<sup>[21]</sup> actions which help in controlling the systemic infection of different origins.[21] Pippali, Haritaki, Punarnava, Amalaki and Madhu have immunomodulatory activity<sup>[22]</sup> which helps in eliminating the infection or regulating the allergic responses.<sup>[23]</sup> On long-term usage, these also potentiate immune system as a whole and prevent recurrence or decrease the magnitude manifestation of infections and allergic phenomenon. The probable action of the drug against allergic response may be by causing an immunological shift from IgE type humoral response toward an IgG or Ig-M type response against invading antigen. The clinical study also supported the action of Kasahara Dashemani group of drugs on the humoral mechanism of immunity.

The control drug Indukanta Vati has ingredients which can be divided in to three sets. The first one is Dashamoola which is a well-known Vatahara, Shothahara, and Rasayana; whereas the other group contains Panchakola which is Ushna, Teekshna, and Vatakaphahara. The third group contains other drugs namely Puteeka, Devadaru, and Yavakshara each having different pharmaco-therapeutic actions. The drug is administered with Madhu as an adjuvant. The antitussive action of the drug is similar to that of Kasahara Dashemani Vati. Here, Madhu and Dashamoola which have additional Shothahara property act locally to alleviate the Shotha in Kantha. Panchakola exhibits its Pachana and Dipana properties and remove Ama; it also causes Sroto Shodhana and clears up all the bodily channels. The restoration of Agni improves digestion, assimilation and metabolism. As Dhatu Preenana is optimized, there will be unobstructed production of subsequent Dhatu. Ultimately, the essence of all Dhatu "Ojas" will be nourished and thus improve Sharira Bala and Vyadhikshamatva.

In modern perspective, the mode of action can be explained as follows. The drugs such as *Devadaru*, *Yavakshara*, and *Madhu* have *mucolytic*, expectorant, and demulcent properties; the constituent drugs of *Panchakola* act as pharyngeal counter irritants and block the receptors of cough reflex and through collective mechanism, they act as immediate cough relievers. The drugs of *Dashamoola* (*Bilva*, *Agnimantha*, *Gambhari*, *Shyonaka*, *Gokshura*, *Prishniparni*), *Puteeka*, and *Devadaru* possess anti-inflammatory action and these help in reducing the inflammation of the respiratory tract.<sup>[24]</sup> Majority of the

drugs (*Devadaru*, *Puteeka*, *Agnimantha*, *Patala*, *Kantakari*) of this formulation have antiviral, antibacterial, or antimicrobial actions which help in eliminating systemic infection. On long-term intake, because of efficient digestion and assimilation, the body gets adequate nutrition. As the body metabolism is normalized by the action of *Panchakola*, there is less production of free radicals.<sup>[25]</sup>

# Conclusion

Kasahara Dashemani Vati was more effective in Vata Pradhana and Pitta Pradhana Kasa, showed better action on RRTI with primarily allergic etiology and was marginally better than Indukanta Vati in improving Vyadhikshamatva/ Bala, even though both have a significant effect. Whereas Indukanta Vati was better in Kapha Pradhana Kasa and on RRTI with primarily infective etiology. When considering specific immune-modulation on humoral immunity, Kasahara Dashemani is the better drug of choice when compared to Indukanta Vati.

# **References**

- Atkins D, Leung DY. Diagnosis of allergic diseases. In: Behrman RE, Kliegman RM, Jenson HB, editors. Nelson's Textbook of Pediatrics. Vol. 1, 18<sup>th</sup> ed. Philadelphia: Saunders Elsevier; 2008. p. 938.
- Eggenberger K. Les infections des voies respiratoires les plus fréquentes chez benfant dans la pratique ambulatoire [Respiratory tract infections most frequently seen in pediatric outpatient care]. Ars Med 1993;83:24-40.
- Kvaerner KJ, Nafstad P, Jaakkola JJ. Upper respiratory morbidity in preschool children: a cross-sectional study. Arch Otolaryngol Head Neck Surg 2000;126:1201-6.
- Agnivesha. Charaka Samhita, Commentary, Chikitsa Sthana, Kasa Chikitsa Adhyaya (18/11). In: Yadavji Trivikramji Acharya, editor. Varanasi: Chaukhambha Sanskrit Sansthan; 2009. p. 540.
- Hibbert J. Tonsils and Adenoids. In: Kerr AG, editor. Scott. Brown's Otolaryngology. Vol. 6, 5<sup>th</sup> ed. London: Butterworths and Co. Ltd.; 1987. p. 368-83.
- Kvaerner KJ, Nafstad P, Jaakkola JJ. Upper respiratory morbidity in preschool children: a cross-sectional study. Arch Otolaryngol Head Neck Surg 2000;126:1201-6.
- Maw AR. Otitis media with effusion. In: Kerr AG, editor. Scott. Brown's Otolaryngology. Vol. 6, 5<sup>th</sup> ed. London: Butterworths and Co. Ltd.; 1987. p. 157-76.
- 8. Kay AB. Allergy and allergic diseases. N Engl J Med 2001;344:30 and 109.
- Hill DJ, Hosking CS, Heine RG. Clinical spectrum of food allergy in children in Australia and South-East Asia: identification and targets for treatment. Ann Med 1999;31:272-81.
- Agnivesha. Charaka Samhita, Commentary, Charaka Samhita, Nidanasthana Apasmaranidana Adhyaya (8/19). In: Yadavji Trivikramji Acharya, editor. Varanasi: Chaukhambha Sanskrit Sansthan; 2009. p. 227.
- Ghai OP. Normal growth and its disorders. In: OP Ghai, Vinod KP, Arvinb B, editors. GHAI Essential Pediatrics. 7th ed. New Delhi: CBS Publishers and Distributors; 2009. p. 2.
- Agnivesha. Charaka Samhita, Commentary, Charaka Samhita, Sutrasthana Shdvirechanashatashritiya Adhyaya (4/16). In: Yadavji Trivikramji Acharya, editor. Varanasi: Chaukhambha Sanskrit Sansthan; 2009. p. 34.
- Sharma R, Sharma S. Gritadhikarana. In Sahasrayogam. Jawahar Nagar, Delhi: Chowkambha Sanskrit Pratisthana; 2004. p. 42.
- Sharangadhara. Sharangadhara Samhita, Commented by Adamalla, Madhyama Khanda, Vati Kalpana Adhyaya (7/5). Pandit Parashurama Shastri, editor. Varanasi: Chaukhambha Orientalia Publications; 2008. p. 196.

- Schaad UB. Prevention of paediatric respiratory tract infections: emphasis on the role of OM-85. Eur Respir Rev 2005;14:95,74-7.
- Suekawa M, Ishige A, Yuasa K, Sudo K, Aburada M, Hosoya E. Pharmacological studies on ginger. I. Pharmacological actions of pungent constitutents, (6)-gingerol and (6)-shogaol. J Pharmacobiodyn 1984;7:836-48.
- Tripathi KD. Drugs acting on skin and mucous membrane. In: Essentials of Medical Pharmacology. Ch. 62, 5<sup>th</sup> ed. New Delhi: Jaypee Brothers Medical Publishers; 2004. p. 795.
- Available from: http://www.finecurepharma.com/cough-suppressants.htm. Last accessed on 21-03-2012.
- Johri RK, Thusu N, Khajuria A, Zutshi U. Piperine-mediated changes in the permeability of rat intestinal epithelial cells. The status of gamma-glutamyl transpeptidase activity, uptake of amino acids and lipid peroxidation. Biochem Pharmacol 1992;43:1401-7.
- Fox AJ, Barnes PJ, Venkatesan P, Belvisi MG. Activation of large conductance potassium channels inhibits the afferent and efferent function of airway

sensory nerves in the guinea pig. J Clin Invest 1997;99:513-9.

- Zhong Y, Zuo C, Li F, Ding X, Yao Q, Wu K, et al. Chemical constituents of Phyllanthus urinaria L. and its antiviral activity against hepatitis B virus. Zhongguo Zhong Yao Za Zhi 1998;23:363-4, 384.
- Suja RS, Nair AM, Sujith S, Preethy J, Deepa AK. Evaluation of immunomodulatory potential of *Emblica officinalis* fruit pulp extract in mice. Indian J Anim Res 2009;43:103-6.
- Saeed S, Tariq P. Antibacterial activities of *Emblica officinalis* and *Coriandrum sativum* against Gram-negative urinary pathogens. Pak J Pharm Sci 2007;20:32-5.
- Singh RS, Ahmad M, Wafai ZA, Seth V, Moghe VV, et al. Anti-inflammatory effects of Dashmula: An Ayurvedic preparation, versus Diclofenac in animal models. J Chem Pharm Res 2011;3:882-8.
- Guo P, Xu J, Xu S, Wang K. Inhibition of hydrogen peroxide production on chondrocytes induced by fulvic acid by ginger volatile oil. Zhongguo Zhong Yao Za Zhi 1997;22:559-61.

# हिन्दी सारांश

# बाल्य कास एवें व्याधिक्षमत्व पर कासहर दशेमानी वटी का प्रभाव

# नयनकुमार सुब्रह्मण्य, कल्पना एस. पटेल, राजगोपाल श्रीक्रिष्ना, विरेन्द्रकुमार कोरी

बाल्यावस्था में पाये जाने वाली व्याधियों मे कास एक सामान्य रोग है । अधिकतम बालकों में अल्प व्याधिक्षमत्व के कारण यह रोग बार बार होता है । अतः कास व्याधि की चिकित्सा करते वक्त कास और व्याधिक्षमत्व दोनो को ध्यान मे लेना अत्यावश्क है । उपरोक्त रोगियों में कास एवं व्याधिक्षमत्व के ऊपर कासहर दशेमानी वटी का प्रभाव जानने के मुख्य ध्येय से यह चिकित्सकीय अध्ययन किया गया है । इस अध्ययन मे कुल ४०, (तीन से १२ वर्ष तक की आयु वाले) कास रोगियों को चयनित करने के बाद रेन्डमैसेशन द्वारा २० रोगियों के दो समूह मे विभाजित किया गया । पश्चात एक समूह को शारीरिक भार अनुरूप (क्लार्कस् रूल द्वारा) उचित मात्रा में कासहर दशेमानि वटी को मधु के साथ ६० दिन तक दिया गया । चिकित्सा के पश्चात हर रोगी में कास की पुनरावृत्ति को जानने के लिये पुनः ६० दिनों तक नियमित परीक्षण में रखा गया । दूसरे समूह को इन्दुंकान्त वटी कन्ट्रोल ड्रग के रूप मे उसी विधि से दी गई । दोनो समूह के रोगियो पर पाये गये परिणामो के तुलनात्मक अध्ययन से यह पता चला है की कासहर दशेमानि वटी सभी प्रकार के कास में अत्युत्तम परिणाम देती है एवं व्याधिक्षमत्व को बढाकर पुनरावृत्ति को भी प्रायशः रोकती है । सांख्यकी आंकलन के अनुसार कासहर दशेमनि वटी (ट्रायल ड्रग) एवं इन्दकान्त वटी (कन्ट्रोल ड्रग) के परिणाम हाइली सिग्निफिकेंट पाये गये है । और परस्पर तुलना मे अधिक अन्तर नहीं पाया गया है ।