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A CLINICAL STUDY TO ASSESS THE EFFICACY OF SHWASAHARA DASHEMANI GHANAVATI IN CARDIAC ASTHMA W.S.R L.V.F

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ABSTRACT

Introduction: *Shwasa* is said as *Shigrapranahara Roga*. It occurs as the main disease and also a symptom in various diseases. *Shwasakruchrata* is a common symptom that occurs in *Hrudroga*. *Acharya Charaka* mentioned the unique classification of drugs based on their action. *Shwasahara Dashemani* is one among them. It is containing 10 herbal drugs which are specially indicated in *Shwasa Roga.* Hence to evaluate the efficacy of *Shwasahara Dashemani* in *Lakshana Roopi Shwasa* in L.V.F (Cardiac Asthma) has taken for the study. **Aim and Objective:** The objective is to assess the efficacy of *Shwasahara Dashemani* in L.V.F with dyspnea (Cardiac Asthma). **Method:** The present study is a controlled comparative, open-label, clinical trial with pre and post-test design. A total of 40 subjects of a diagnosed case of L.V.F with dyspnea (Cardiac Asthma) were selected by using a simple random sampling method. Control group subjects were intervened with standard treatment of L.V.F and intervention group subjects were intervened with standard treatment of L.V.F along with *Shwasahara Dashemani Ghana Vati*, for the duration of 30 days. Its efficacy was assessed before treatment (0^{th} day) and after treatment (31^{st} day) by using BDI (Baseline

Dyspnea Index Scale). **Results**: The P-value of dyspnea of the control group is 1.000 and the P-value of dyspnea of the intervention group is 0.105. This shows that the results of both groups are statistically not significant. But as compared to the control group, the intervention group is clinically significant because after the intervention 35% of subjects had shown improvement in the intervention group. **Conclusion:** As compared to the control group, in the intervention group *Shwasahara Dashemani Ghanavati* is clinically significant in relieving cardiac asthma when used with standard treatment of L.V.F.

Keyword: *Shwasahara Dashemani*. Cardiac Asthma, L.V.F, Dyspnea

INTRODUCTION

Shwasa is the *Pranavahasroto Vyadhi* [1]. It will occur both as the main disease and symptom in many diseases. It is also one of the common symptoms of *Hrudroga* (heart disease) [2]. Heart failure is a complex clinical syndrome that results from structural or functional impairment of ventricular filling or ejection of blood, which in turn leads to the cardinal symptoms dyspnea and fatigue and signs of heart failure namely edema and rales.[3] Cardiac Asthma means dyspnea with expiratory wheeze which occurs in cardiac disease. *Acharya Charaka* has mentioned a group of 10 drugs especially for *Shwasa*, which are named as *Shwasahara Dashemani* based on the *Karma* i.e, *Shwasaharatwa*.[4] Hence to evaluate the efficacy of *Shwasahara Dashemani* in *Lakshana Roopi Shwasa* in L.V.F (Cardiac Asthma) has taken for the study.

The objective of the Study

The objective is to assess the efficacy of *Shwasahara Dashemani* in L.V.F with dyspnea (Cardiac Asthma)

Materials and Methods

The present clinical intervention has been cleared by the Institutional Ethics Committee with reference no IRC-EC/SS (3)/2018-2019 Dated on March 22, 2019, and also, the present clinical intervention was registered in CTRI (Clinical Intervention Registry of India), CTRI registration number is **CTRI/2021/04/032624.**

Source of data and Study design

For the present study, the source of data was selected from the OPD and IPD of GAMC, Mysore and Vidyaranya multi-speciality Hospital, Chamundipuram, Mysore. The research design is a controlled comparative, open-label, clinical trial with pre and post-test design. A total of 44 subjects were registered, there were 4 dropouts. The study was completed in 40 subjects i.e 20 subjects in the control group and 20 subjects in the intervention group and data of 40 subjects were collected.

Inclusion Criteria

- Diagnosed case of L.V.F with Dyspnea (Ejection Fraction 35-39%)
- Subjects with diagnosed cases of L.V.F with the age of 40 to 60 years, irrespective of gender were included in the study.

Exclusion Criteria

- Subjects with the life-threatening type of L.V.F with EF less than 35% associated with complications

Intervention

20 subjects of the control group were intervened with standard treatment (Allopathic) of L.V.F. i.e Angiotensin-converting enzyme inhibitors, Beta Blockers, Angiotensin Receptor Blockers, Aldosterone receptors blockers, Arteriovenous Vasodilators and Diuretics.

20 subjects with the intervention group were intervened with standard treatment (Allopathic) of L.V.F along with *Shwasahara Dashemani Ghana Vati*, 3gm/day (6 tablets-500mg each) in 3 divided doses after the food along with warm water for the duration of 30 days. Data was collected before intervention (0^{th} day) and after treatment (31^{st} day).

Intervention Drug: The intervention drug *Shwasahara Dashemani Ghanavati* was procured from GMP certified company i.e. Vishwachaitanya Ayurvediya Rasashala, Baramati, Pune, Maharashtra. Quality analysis of the finished product was done. Details of *Shwashahara Dashemani* drugs and their scientific name, Family, Preclinical outcome and *Rasapanchaka, Doshaghna Karma* is shown in Table 1 and 2.

Table 1: *Shwasahara Dashemani* drugs, their scientific name, Family and Preclinical Outcome

Sl No	Sanskrit Name	Scientific Name	Family	Part Used	Preclinical outcomes
1	Shati	Hedychium spicatum Ham.Ex Smith	Zingiberace	Rhizome	Analgesic and Anti-Inflammatory action, antimicrobial action. [5]
2	Pushkara Moola	Inula racemose Hook.F.	Astracea	Root	**Cardioprotective action**, Adrenergic Beta Blocking action, Antiallergic action, Anti-inflammatory & Analgesic action.[6]
3	Amlavetas	Garcinia pedunculate Roxb.	Guttiferae	Dried fruit rind	-
4	Ela	Elettaria cardamomum Maton.	Zingiberacae	Seeds	Bronchodilator action [7]
5	Hingu	Ferula narthex Boiss	Umbelliferae	Gum resin	**Antihypertensive action**, Smooth muscle relaxant action, **Anti-coagulant action** & Antispasmodic action.[8]
6	Aguru	Aquilaria agallocha Roxb	Thymelaeaceae	Heartwood	Anti-microbial action [9]
7	Surasa	Ocimum santum Linn	Lamiaceae	Whole plant	Anti-microbial action, **Immunologic action**, Anti-anaphylactic, Antihistaminic and Mast cell stabilizing action & **cardio protective action** [10]
8	Tamalaki	Phyllanthus Niruri Linn	Euphorbiaceae	Whole plant	-
9	Jivanti	Lepdenia reticulata W & A.	Asclepiadaceae	Whole plant	Antibacterial action, Anti-asthmatic action (Antihistaminic action).[11]
10	Chanda	Angelica glauca Edgew	Apiaceae	Root	Antimicrobial action, Inhibition of **Acetylcholinesterase action**.[12]

Table 2: Showing the Rasapanchaka of Shwasahara Dashemani

Rasa	No of Drugs	Shwasahara Dashemani Drugs
Katu	8	Shati, Pushakaramuala, Hingu, Aguru, Surasa, Tamalaki, Chanda, Ela
Tikta	5	Shati, Pushkaramula, Aguru, Chanda, Tulasi
Kashaya	2	Shati, Tamalaki
Madhura	2	Tamalaki, Jivanti
Amla	1	Amlavetasa
Guna		
Laghu	9	Shati, Pushakaramuala, Hingu, Aguru, Surasa, Tamalaki, Chanda, Ela, Amlavetasa
Rooksha	5	Amlavetasa Surasa, Tamalaki, Chanda, Ela
Tikshna	5	Shati, Pushkaramula, Agaru, Chanda, hingu
Snigdha	2	Jivanti, Agaru
Virya		
Ushna	8	Shati, Pushakaramuala, Hingu, Aguru, Surasa, Amlavetasa, Chanda, Ela
Sheeta	2	Tamalaki, Jivanti
Vipaka		
Katu	7	Shati, Pushakaramuala, Hingu, Aguru, Surasa, Chanda, Ela
Madhura	2	Tamalaki, Jivanti

Amla	1	Amlavetasa,
Doshaghna Karma		
Vata-Kapha Shamaka	7	Shati, Pushakaramuala, Hingu, Aguru, Surasa, Chanda, Amlavetasa,
Tridosha-Shamaka	2	Ela, Jivanti
Pitta-Kapha Shamaka	1	Tamalaki
Pittavardhaka	3	Hingu, Agaru, Tulasi

Assessment

Data were collected before starting the treatment, after the completion of the intervention. The duration of the study was 30 days with pre-assessment on 0th day and post-assessment on the 31st day

Assessment parameters

The findings were subjected to analysis before and after the intervention by using BDI (Baseline Dyspnea Index Scale) is shown in Table 3

Table 3: Baseline Dyspnea Index Scale [13]

Baseline Functional Impairment		
Grade1	Severe impair-ment	Subject unable to work /has given up most or all usual activities due to shortness of breath
Grade 2	Moderate impair-ment	Subject has changed jobs and /or has abandoned at least one usual activity due to shortness of breath
Grade 3	Slight impair-ment	Distinct impairment in at least one activity but no activities completely abandoned. Reduction, inactivity at work or in usual activity, that seems slight or not caused by shortness of breath
Grade 4	No impair-ment	Able to carry out usual activity and occupation without shortness of Breath
Baseline Magnitude of Task		
Grade1	Light	Becomes short of breath with light activities such as walking on the level, washing or standing.
Grade 2	Moderate	Becomes short of breath with moderate or average tasks such as walking up a gradual hill, climb-ing fewer than three flights of stairs, or carrying a light load on the level.
Grade 3	Major	Becomes short of breath only with major activities as walking up a steep hill, climbing more than three flights of stairs, or carrying a moderate load on the level
Grade 4	Extraordi-nary	Becomes short of breath only with extraordinary activity such as carrying very heavy loads on the level, lighter load uphills, or running. No Shortness of breath with ordinary tasks
Baseline Magnitude of Effort		
Grade1	Light	Becomes short of breath with little effort. Task performed with little effort or more difficult tasks performed with frequent pauses and requiring 50-100 % longer to complete than the average per-son might require.
Grade 2	Moderate	Becomes short of breath with moderate effort. Tasks are performed with occasional pauses and require longer to complete than the average person.
Grade 3	Major	Becomes short of breath effort distinctly submaximal, but of major portion. Tasks are performed without pause unless the task requires an extraordinary effort that may be performed with pauses.
Grade 4	Extraordi-nary	Becomes short of breath only with the greatest imaginable effort. No shortness of Breath with ordinary effort

Statistical Methods

The results of the present study were analyzed statistically by applying inferential statistical methods. The software used is SPSS Version 16.0

Results: Distribution of subjects based on the severity of overall symptoms of BDI scale before and after the treatment as shown in Tables No-4 and 5.

Table 4: Results of Baseline Functional Impairment before and after the treatment

Groups		BFI		Total
		Moderate	Slight	
Control	BT	16 (80.0%)	4 (20.0%)	20 (100.0%)
	AT	16 (80.0%)	4 (20.0%)	20 (100.0%)
Intervention	BT	15 (75.0%)	5 (25.0%)	20 (100.0%)
	AT	9 (45.0%)	11 (55.0%)	20 (100.0%)

Table 5: Results of Baseline Magnitude of Task and Baseline Magnitude of Effort before and after the treatment

Groups		BMT and BME		Total
		Moderate	Major	
Control	BT	16 (80.0%)	4 (20.0%)	20 (100.0%)
	AT	16 (80.0%)	4 (20.0%)	20 (100.0%)
Intervention	BT	15 (75.0%)	5 (25.0%)	20 (100.0%)
	AT	9 (45.0%)	11 (55.0%)	20 (100.0%)

In the control group, there was no change in BFI, BMT and BME before and after the intervention. In the intervention group after the intervention, 35% of the subjects had reported improvement in BFI, BMT and BME.

Statistics – Pearson chi-square test

P-Value and significance of both control group and intervention group in relieving dyspnea is given in Table 6

Table 6: Statistical significance of Dyspnea, Control and Intervention Group

Parameters	Control group		Intervention group		Statistical Test
	P-value	Remarks	P-value	Remarks	
BFI	1.000	Statistically not Significant	0.105	Statistically not Significant	Pearson chi-square Fisher's exact test
BMT					
BME					

DISCUSSION

Dyspnea is a subjective experience of breathing discomfort, that consists of qualitatively distinct sensations that are very in intensity.[14] In L.V.F the left ventricle of the heart has no longer pumps enough blood. As a result, blood builds up in the pulmonary veins, which causes dyspnea. Orthopnea and Paroxysmal Nocturnal Dyspnea (PND) are the clinical symptoms of Heart Failure (HF) with reduced ejection fraction, and it is treated with Angiotensin-converting enzyme inhibitors, Beta Blockers, Angiotensin Receptor Blockers, Aldosterone receptors blockers, Arteriovenous Vasodilators and Diuretics. The preclinical outcome of *Shwasahara Dashemani* is known for their activities such as cardioprotective action and Inhibition of Acetylcholinesterase action. Cardioprotective action includes improvement in the precordial pain and dyspnea, a significant reduction in cholesterol, triglycerides and total lipid level. Improve antioxidant status, hemodynamic and left ventricular contractile function subsequent to suppression of oxidative stress.

It was observed that, during the trial period as compared to the control group, 65 % of subjects of the intervention group, have reported increased frequency of urination as compared to the baseline period. *Karma* of *Mutra* is *Kledavahana* (removal of excessive *Kleda*) it can be correlated with diuretic action.

Hrudaya is the *Moola* of *Pranavaha* and *Rasavaha Srotas*, any abnormality in the *Hrudaya* leads to vitiation of *Pranavaha* and *Rasavaha Srotas*, in turn, leads to *Shwasa* in *Hrudroga. Sthana* of *Vyanavayu* is *Hrudaya*, vitiation of this leads to *Hrudroga*. Among *Shwasahara Dashemani* most of the drugs have *Ushna Virya, Kaphavatahara, Deepana, Pachana* and *Anulomana* properties. *Ushna Virya* and *Anulomana* action of *Shwasahara Dashemani* helps in *Hrudroga.*

Shwasa is the *Pittashtana Samudbhava, Kaphavata Pradhana Vyadhi* and derangement of *Agni* is there, *Shwasahara Dashemani* acts on all these components which are involved in the manifestation of *Shwasa*.

Both *Shwasa* and *Hrudroga* are *Amashaya Samudbhava Vyadhi*, *Deepana* and *Pachana* action of *Shwasahara Dashemani* helps in *Lakshana Roopi Shwasa* of *Hrudroga*

Haratwa property of *Shawsa* is to be understood by this. *Karma* which relieves the *Shwasa* is called *Shawsahara Dasheamani*.

Here in this study sample size is small and two nominal variables are there, hence Pearson chi-square Fisher's exact test is used for statistical analysis.

The P-value of dyspnea of the control group is 1.000 and the P-value of dyspnea of the intervention group is 0. 105. This shows that the results of both groups are statistically not significant. But as compared to the control group, the intervention group is clinically significant because after the intervention 35% of subjects had shown improvement in the intervention group.

CONCLUSION

As compared to the control group, in the intervention group *Shwasahara Dashemani Ghanavati* is clinically significant in relieving cardiac asthma when used with standard treatment of L.V.F. Thus, *Shwasaharatwa Karma* of *Shwasahara Dashemani* is clinically significant and evident in *Lakshana Roopi Shwasa* in *Hrudroga* (L.V.F with dyspnea).

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