



**CLINICAL STUDY ON THE EFFICACY OF PHALATRIKADI
GHANAVATI IN THE MANAGEMENT OF MADHUMEHAJANYA
MEDOROGA WITH SPECIAL REFERENCE TO *DIABETIC*
DYSLIPIDAEMIA**

**Dr. Hemlata Soni^{1*}, Dr. Udai Raj Saroj², Dr. Ajay Kumar Sahu and Dr. Sashi Mohan
Sharma**

¹M.D. (Ay). Scholar, P.G. Department of Kayachikitsa, NIA, Jaipur.

²Associate Professor, P.G. Department of Kayachikitsa, NIA, Jaipur.

³Assistant Professor, P.G. Department of Kayachikitsa, NIA, Jaipur.

⁴M.D. (Med.), D.N.B.(Cardio.)Sr. Professor and Unit Head Department of Cardiology S.M.S.
Hospital & Medical College, Jaipur.

Article Received on
25 August 2018,

Revised on 16 Sept. 2018,
Accepted on 06 Oct. 2018

DOI: 10.20959/wjpps201811-12543

***Corresponding Author**

Dr. Hemlata Soni

M.D. (Ay). Scholar, P.G.
Department of Kayachikitsa,
NIA, Jaipur.

ABSTRACT

Meda is the main Dushya in Madhumeha. The Nidana of Madhumeha and Medodushti is also similar. So Madhumehi patients may also suffer from Medoroga. Thus while treating the Madhumehajanya Medoroga, selection of Dravya should have criteria that help in Lekhana of excessive Meda-Kapha without Vayu-Prakopa & normalising the Agni both at the level of Jatharagni & Dhatwagni. Thus, the present study was planned & carried out on 15 clinically diagnosed & investigated individuals of *Diabetic* Dyslipidaemia. Patients were selected from OPD & IPD of NIA, Jaipur. Each one

administered Phalatrikadi Ghanavati in dose of 2 tablet (each tab.500 mg) for 30 days.

KEYWORDS: Madhumeha, Medoroga, *Diabeties*, Dyslipidaemia, Phalatrikadi Ghanavati.

INTRODUCTION

Ayurveda classics describe two types of *Pramehi*. One is *Sthoola* and other is *Krishha Pramehi*.^[1] There is role of *Dhatukshaya* in *Krishha Pramehi* which can be correlated with type 1 diabetes. In *Sthoola Pramehi* there is *Margavarodha Janya Vata Prakopa* in which *Tridosha* and ten *Dushya* get involved, of which particularly *Meda dhatu & Kapha Dosha*

vitiation leads to condition “*Abaddha Meda*” or “*Bahul Drava Shleshma*” due to *gunasamanya Medodhatu* majorly affected which can be correlated with diabetic dyslipidaemia. Dyslipidaemia is a disorder of lipoprotein metabolism, which can include overproduction or deficiency of lipoproteins or both.^[2] Many types of Dyslipidaemia carry an increased risk of cardiovascular disease.^[3] High-density-lipoprotein (HDL) cholesterol however confers protection. The composition of lipid particles in diabetic Dyslipidaemia is more atherogenic than in Dyslipidaemia in general.^[4]

MATERIALS AND METHODS

Aims & Objectives

1. Conceptual and clinical studies on Diabetic Dyslipidaemia & *Madhumehajanya Medoroga*.
2. To assess the clinical efficacy of *Phalatrikadi Ghanavati* in the management of series of patients of *Madhumehajanya Medoroga* (Diabetic Dyslipidaemia).

Inclusion Criteria

- (a) Patients willing to sign the consent form.
- (b) Patients between the age group of 20-60 years of either sex.
- (c) Diagnosed and confirmed cases of Dyslipidaemia in Diabetes Mellitus Type II patients (based on NCEP-Adult treatment panel III guideline) Total Cholesterol (TC) > 200 mg/dl, Triglyceride (TG) > 150 mg/dl, Low Density Lipoprotein (LDL) > 130 mg/dl, High Density Lipoprotein (HDL) < 40 mg/dl, Fasting blood sugar (FBS) <140 mg/dl, Post Prandial blood sugar (PPBS) < 200 mg/dl.

Exclusion Criteria

- a) Patients having Type - DM I [IDDM]
- b) Patient of type II DM who were on Insulin therapy.
- c) DM with Coronary Artery Diseases (CAD), Malignancy or any other serious illness.
- d) DM with serious complications.
- e) Diabetes Insipidus.
- f) Drug induced DM.
- g) Fasting Blood Sugar >140mg/dl.
- h) Postprandial Blood Sugar >200mg/dl.
- i) Uncontrolled Hypertension (systolic blood pressure>150 mm of Hg and /or Diastolic blood pressure >100 mm of Hg).

Administration of Drug

15 patients were administered Trial Drug *Phalatrikadi Ghanvati* in the dose of 2 tablet (each tab.500 mg) twice a day before meal, with lukewarm water for 30 days.

Table No. i: Contents of *Phalatrikadi Ghanavati*^[5]

S. N.	Name of drug	Latin Name	Proportion	Part used
1.	Amalaki	Emblica officinalis	1 Part	Fruit
2.	Haritaki	Terminalia chebula	1 Part	Fruit
3.	Bibhitaki	Terminalia bellerica	1 Part	Fruit
4.	Darunisha	Berberis aristata	1 part	Root
5.	Vishala	Cirullus colocynthis	1 part	Fruit
6.	Mustakaa	Cyperus rotundus	1 Part	Rhizome
7.	Haridra	Curcuma longa	2 Part	Rhizome

Criteria for Assessment

1. Subjective Parameter

<p>Symptom of <i>Medodushti</i>^[6]</p> <ul style="list-style-type: none"> • <i>Kshudrashwasa</i> (Dyspnoea) • <i>Trishna</i> (Excessive Thirst) • <i>Moha</i> (Syncope) • <i>Atinindra</i> (Excessive Sleep) • <i>Krathana</i> (Snoring) • <i>Angasada</i> (Lethargy) • <i>Atikshudha</i> (Excessive Hunger) • <i>Swedadhikya</i> (Excessive Sweating) • <i>Daurgandhya</i> (Foul Odour) • <i>Alpaprana</i> (Generalized Weakness) • <i>Alpamaithuna</i> (Sexual Weakness) 	<p>Symptom of <i>Madhumeha</i>^[7] –</p> <ul style="list-style-type: none"> • <i>Sthoulya</i> (Obesity) • <i>Pipasa</i> (Polydypsia) • <i>Avila Mutrata</i> (Turbid Urine) • <i>Prabhoot Mutrata</i> • <i>Tandra</i> (Drowsiness) • <i>Hastpadtala Daha</i> (Burning Sensation In Palm and Soles) • <i>Sada</i> (Lethargy) • <i>Panduvarna Mutra</i>(Yellowish White Urine)
---	--

Assessment of all the above symptoms will be done by using “Symptom Rating Scale” as following.

Symptoms	Score
Absent	0
Mild	1
Moderate	2
Severe	3

2. Objective Parameter

a. Body weight

- b. Body Mass Index (BMI)
- c. Waist- Height Ratio
- d. Waist- Hip Ratio

3. Investigation parameter

a. Haematological

Haemoglobin (gm %)

Erythrocyte sedimentation rate (ESR) in mm/hour.

b. Bio-chemical

Serum Total cholesterol (TC)

Serum Triglycerides (TG)

Serum Low Density Lipoprotein (LDL)

Serum Very Low Density Lipoprotein (VLDL)

Serum High Density Lipoprotein (HDL)

C-Reactive Protein Test

Fasting Blood Sugar (F.B.S)

Postprandial Blood Sugar (P.P.B.S)

Glycosylated Hemoglobin (HbA1c)

Statistical Analysis

- All the Results calculated by using software InStat graph pad 3.1.
- For Nonparametric Data Wilcoxon matched-pairs signed ranks test was used while for Parametric Data & Anthropometric Parameters Paired 't' Test was used.
- Level of significance was carried out at the p value interpreted as following- Non-significant: $P > 0.05$.
- Significant: $P < 0.05$.
- Highly significant: $P < 0.01$, $P < 0.001$, $P < 0.0001$.

OBSERVATIONS AND RESULTS

Table No. ii: Shoeing Effect of Therapy in Subjective Parameters.

Sign & Symptoms	Mean		MeanDiff.	% Relief	SD±	SE±	P	S
	BT	AT						
Kshudrashwasa	1.333	0.9333	0.4000	30.00	0.5071	0.1309	<0.05	S
Trishna	0.8000	0.4667	0.3333	41.66	0.4880	0.1260	>0.05	NS
Moha	1.000	0.7333	0.2667	26.67	0.4577	0.1182	>0.05	NS
Atinindra	0.9333	0.4667	0.4667	50.00	0.5164	0.1333	<0.05	S
Krathana	1.333	1.133	0.2000	15.03	0.4140	0.1069	>0.05	NS
Angasada	1.933	1.400	0.5333	27.58	0.5164	0.1333	<0.01	HS
Atikshudha	0.5333	0.2000	0.3333	62.53	0.4880	0.1260	>0.05	NS
Swedadhikya	1.1333	0.8667	0.2667	23.53	0.4577	0.1182	>0.05	NS
Daurgandhya	0.8000	0.6000	0.2000	25	0.4140	0.1069	>0.05	NS
Alpaprana	1.467	1.067	0.4000	27.39	0.5071	0.1309	<0.05	S
Alpamaithuna	1.733	1.600	0.1333	7.70	0.3519	0.09085	>0.05	NS
Sthoulya	1.467	1.400	0.06667	4.56	0.2582	0.0667	>0.05	NS
Avila Mutrata	0.7333	0.4667	0.2667	36.38	0.4577	0.1182	>0.05	NS
Prabhoot Mutrata	0.800	0.4667	0.3333	41.66	0.4880	0.1260	>0.05	NS
Tandra	1.267	0.8000	0.4667	36.8	0.5164	0.1333	<0.05	S
Hastpadtala Daha	0.6667	0.4000	0.2667	40.04	0.4577	0.1182	>0.05	NS
Panduvarna Mutra	1.067	0.7333	0.3333	31.23	0.4880	0.1260	>0.05	NS

(HS: Highly Significant; S: Significant; NS: Non Significant)

Table No. iii: Showing Effect OF Therapy For Objective Parameters.

Variables	Mean		MeanDiff.	%Relief	SD±	SE±	T	P	S
	BT	AT							
Hb %	13.633	13.813	0.1800	1.3	0.5882	0.1519	1.185	>0.05	NS
ESR	26.467	18.533	7.933	29.96	17.588	4.541	1.747	>0.05	NS
Sr. Total cholesterol	244.93	198.20	46.733	19.07	31.874	8.230	5.679	<0.0001	HS
Sr. Triglycerides	209.27	153.67	55.600	26.56	58.439	15.089	3.685	<0.01	HS
Sr.LDL	152.48	118.27	34.213	22.43	27.891	7.201	4.751	<0.001	HS
Sr.VLDL	41.840	30.667	11.173	26.69	11.627	3.002	3.722	<0.01	HS
Sr.HDL	50.56	49.733	0.8267	1.63	5.432	1.403	0.5894	>0.05	NS
F.B.S.	129.33	123.60	5.733	4.43	8.388	2.166	2.647	<0.05	S
P.P.B.S.	183.33	174.87	8.467	4.61	8.175	2.111	4.011	<0.01	HS
HbA1c	6.153	6.013	0.1400	2.27	0.2414	0.06234	2.246	<0.05	S
C.R.P.*	0.33	0.33	-	-	-	-	-	-	-

*Statistical test is not applicable because BT & AT values are same.

Table No. iv: Showing Effect of Therapy For Anthropometric Parameters.

Variables	Mean		MeanDiff.	%Relief	SD±	SE±	T	P	S
	BT	AT							
Body Weight (kg)	76.600	74.00	2.600	3.39	1.121	0.2895	8.981	<0.0001	HS
B.M.I. (Kg/m ²)	29.844	28.823	1.021	3.4	0.4654	0.1202	8.493	<0.0001	HS
Waist-Height Ratio	0.6193	0.6120	0.00733	1.18	0.0088	0.0022	3.214	<0.01	HS
Waist-Hip Ratio	0.9527	0.9560	0.0033	0.34	0.02160	0.0055	0.5976	>0.05	NS

(B.M.I.: Body Mass Index; HS: Highly Significant; S: Significant; NS: Non Significant).

DISCUSSION

Maximum contents of the Phalatrikadi Ghanavati have Katu, Tikta and Kashaya Rasa. Katu Rasa has Medonashak property.^[8] It is constituted of predominantly Agni and Vayu Mahabhoot. It augments the Pachakagni subsequently to Medodhatwagni thereby resulting in proper quantity and quality of both Sthayi and Asthayi Medo Dhatu.^[9] Tikta rasa has Medoshoshana property.^[10] It is constituted of Akasha and Vayu Mahabhuta.^[11] & it have Deepana, Pachana, Lekhana, Upashoshana, and Sthirakarana property. By its Deepana property, it augments Jatharagni leading to subsequent increase in the Medodhatwagni thus formation of optimal Meda Dhatu. Kashaya Rasa is the most Ruksha amongst the six Rasa.^[12] By the virtue of its Shoshana property, it absorbs the Medo Dhatu, Kleda, Kapha Dosha thus relieving the Atiprivitti Pathology. It also aids in removing excesskleda present in the body thus performing Kledaharana. Ruksha guna is the opposite of Snigdha guna which is the dominant Guna of Medo dhatu. It causes Stambhana and Kharatva (roughness) thereby bringing about a reduction in the excessively produced Medo Dhatu. Laghu guna is constituted of Akasha, Agni and Vayu mahabhuta in Panchbhautika composition. It has Laghavakara, Kaphaghna and Shighrapakitva property. It also causes Lekhana & Ropana. Due to these properties it alleviates the aggravated Kapha and augmentation of Vata, thereby reducing Gaurava. As regards to Virya, majority of the drugs of Phalatrikadi Ghanavati have Ushna Virya, which opposes any increase in the quantum of Kapha and Medas. Related to Vipaka, majority of these drugs have Katu Vipaka which enhances the Jatharagni and Dhatwagni and normalizes the metabolic process^[13]. It also reduces the Kapha and Meda (fat) content of the body. It is clear that drug Phalatrikadi Ghanavati has Virechanopaga, Triptighna, Lekhaniya, Deepaniya, Pachaniya, Rochana, Anulomana, Kaphaghna, Vayasthapana, and Rasayana properties, which clearly explain its mode of action in Madhumehajanya medoroga.

CONCLUSIONS

- *Phalatrikadi Ghanavati* is more effective in subjective criteria like *Angasada*, *Atinindra* and *Alpaprana*, in objective parameters like serum LDL, P.P.B.S. and HbA1c and in also anthropometric parameters like Body Weight, B.M.I., Waist-Height Ratio.
- The *Ayurvedic* medicine *Phalatrikadi Ghanavati* has not known any side effect during the trial.

REFERENCES

1. Agnivesha, Charka Samhita, Vidyotini Hindi Commentry by K. Shatri, G.N. Chaturvedi, Chaukhabha Bharati Academy Varanasi. Year of reprint 2009, Chikitsasthana 6/15.
2. YP Munjal, SK Sharma et al. API Textbook of Medicine 9th edition, Mumbai, The
3. Association of Physician of India, 2012; 1232-1239.
4. Danial J Rader and Helen H. Hobbs, Harrison's Principles of Internal Medicine, 18 Edition Volume 2, Chapter 356.
5. The journal of clinical Endocrinology & Metabolism, Volume 86, Issue 3, 1 March 2001, 965-971. Available from <https://doi.org/10.1210/jcem.86.3.7304>
6. Shukla V & Tripathi RD, Charaka Samhita, edited with *Vaidyamanorama hindi commentery*, Vol.II, Chaukhambha Snskrit Prakashan, Delhi, Ed., 2012.
7. Commentary by Sri Vijayarakshita and Srikanthadatta. 31st ed. Varanasi: Chaukhambha Sanskrit Sansthana; 2002. Madhava, Madhava Nidana, 34/3.
8. Shukla V & Tripathi RD, *Charaka Samhita*, edited with *Vaidyamanorama hindi commentery*, Vol.I, Chaukhambha Sanskrit Prakashan, Delhi, Ed., 2012.
9. Sushruta, Sushruta Samhita, edited with Ayurveda Tatva Sandipika hindi commentary, by kaviraja Ambikadutta Shastri Part I, Chaunkhambha Sanskrit Sansthan, Varanasi, 12th Ed. Year of print 2009, sutrasthana 42/15.
10. Ibidem (No.i) *Sutra Sthana* chapter 26/ 42.
11. Ibidem (No.X) *Sutra Sthana* chapter 42/16.
12. Ibidem (No.i) *Sutra Sthana* chapter 26/40.
13. Gupta Kavoraj Atrideva, *Astanga Hridayam of Vagbhata* edited with *Vidyotini hindi commentery*, Chaukhanba *Sanskrit* sansthaan, Varanasi, edition 2011. (A.H. Su.10/37)
14. Database on medicinal plants used in Ayurveda, Published by The central council of Research in Ayurveda and Siddha, New Delhi, Year of publication 2000.