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ORIGINAL RESEARCH ARTICLE

Clinical Evaluation of *Vyoshadi Guggulu* and *Haritaki Churna* in the Management of Dyslipidemia

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ABSTRACT

Man has modifying his dietary and lifestyle preferences to suit the modern era and causing multitudes of diseases which are popularly referred as 'lifestyle diseases'. Dyslipidemia is one such life style disorder which is identified as a potential risk factor for multitudes of diseases like cardiovascular diseases etc. Drugs used in modern science to treat dyslipidemia have several adverse effects like myopathy, liver damage, nausea, bowel upset etc. World is looking toward *Ayurveda* for definite & harmless solution to this problem. As compare to *Nidanas* (causative factor) dyslipidemia can be stated under broad umbrella of '*Santarpanjanya Vyadhis'*. *Apatarpana* is the treatment for *Santarpanjanya Vyadhis*. Taking into consideration all the treatment modalities in *Ayurveda*, *Vyoshadi Guggulu*(1gm thrice in day) and *Haritaki Churna* (3gm twice in day)was selected for the management of dyslipidemia in the present study & given for duration of 12 weeks. Total 47 out of 53 patients were completed. After completion of treatment there was remarkable percentage improvement in subjective criteria like breathlessness, parasthesia, confusion, & fatigue. For rest of the objective parameters statistically insignificant results were obtained.

Key words: Dyslipidemia, *Vyoshadi Guggulu, Haritaki Churna.*

INTRODUCTION

Man has adapted himself to the fast paced life by modifying his dietary and lifestyle preferences to suit the modern era. This has resulted in a state of discrepancy between the external environment and his internal mechanism causing multitudes of diseases which are popularly are referred as 'lifestyle diseases'. Fast foods, lack of exercise, stress, various addictions etc. are some of the factors which contribute greatly to such diseases. These factors generally act by impairing the metabolism of an individual making him prone to series of disorders. Dyslipidemia is one such disorder which is identified as a potential risk factor for multitudes of diseases like cardiovascular diseases, metabolic syndrome and even hypertension. Hyperlipidemia is the condition of abnormally elevated levels of any or all lipids and/or lipoproteins in the blood. It is the most common form of dyslipidemia [1,2]. Hyperlipidemia is a condition in which the levels of lipoproteins (cholesterol, triglycerides or both) are raised in the plasma; which can be co- related to raised '*Meda'* in body. Attempts were made by various scholars of *Ayurveda* to clinically co-relate it to *'Raktgatsneha Vriddhi'*, *'Rasraktgatsneha Vriddhi'*, *'Medoroga'*, *'Sthaulya'* etc. Hyperlipidemia is contributed by high fat diet, sedentary lifestyle etc. These *Nidanas* can be compared to use of *Snigdha, Guru, Picchila Guna* and *Chesthadvesha* (lack of physical activity) which leads to *Santarpanajanya Vyadhis* according to *Ayurveda*. Hence hyperlipidemia can be stated under broad umbrella of '*Santarpanjanya Vyadhis'*.

Apatarpan is the treatment for *Santarpanjanya Vyadhis* [3]. Taking into consideration all the treatment modalities in *Ayurveda Haritaki* is given in the line of treatment in *Santarpanjanya Vyadhis* [4]. *Vyoshadi Guggulu* was quoted in the *Sarva Meda Shlesmaj Vyadhi* [5]. So in light of above references from classics *Vyoshadi Guggulu*

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and *Haritaki Churna* was selected for the management of dyslipidemia in the present study.

AIMS AND OBJECTIVES

Primary

- To assess the clinical efficacy of *Vyoshadi Guggulu* and *Haritaki Churna* in the management of dyslipidemia.

Secondary

- To assess the clinical efficacy & safety of *Vyoshadi Guggulu* and *Haritaki Churna* in the patients of dyslipidemia.

Outcome

Primary

- change in lipid profile

MATERIALS AND METHODS

Patients having lipid profile with increased/or elevated lipid profile were selected for present studies. Patients fulfilling the criteria & attending OPD & IPD of *Panchakarma* dept. and cases referred by other departments of IPGT & RA hospital, GAU; were selected irrespective of race, cast, sex, religion etc. Ethical clearances was obtained from ICE.

The trial will be conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki for biomedical research and ICMR ethical guidelines involving human participants (2006), and that are consistent with Indian / ICH Good Clinical Practice (GCP) guidelines.

Study Type : Interventional
Purpose : Treatment
Masking : Open label
Control : Not controlled
Timing : Prospective
End Point : Efficacy and Safety
No. of Groups: One

Inclusion Criteria

1. Patients of either sex aged 18 –70 years.
2. Patients having
   - LDLc 100mg/dl - 160mg/dl
     And / or
   - Total cholesterol 200mg/dl - 250mg/dl
     And / or
   - Triglycerides –150mg/dl - 250 mg/dl
     3. Willing and able to participate for 16 weeks

Exclusion Criteria

1. Patients who have received any cholesterol lowering medication (Modern Drug) within last 8 weeks.
2. Patients having Type III and Type IV hypercholesterolaemia.
3. Patient with poorly controlled Hypertension (> 160 / 100 mm Hg).
4. Patients with evidence of malignancy.
5. Patients on prolonged (> 6 weeks) medication with corticosteoids, antidepressants, anticholinergics, immunosuppressants, oral contraceptive pills or estrogen replacement therapy etc. or any other drugs that may have an influence on the outcome of the study.
6. Patients suffering from major systemic illness necessitating long term drug treatment (Rheumatoid arthritis, Tuberculosis, Psycho-Neuro-Endocrinal disorders, etc.).
7. Patients who have a past history of Atrial Fibrillation, Acute Coronary Syndrome, Myocardial Infarction, Stroke or Severe Arrhythmia in the last 6 months.
8. Symptomatic patient with clinical evidence of Heart failure.
9. Patients having uncontrolled Diabetes Mellitus i.e.HbA1c > 10%.
10. Patients with concurrent serious hepatic disorder (defined as aspartate aminotransferase (AST) and / or alanine aminotransferase (ALT), total bilirubin or alkaline phosphatase (ALP) > 2 times upper normal limit) or renal disorders (defined as S.creatinine >1.2mg/dl), severe pulmonary dysfunction (uncontrolled asthma and chronic obstructive pulmonary disease [COPD]), inflammatory bowel disease or any other condition that may jeopardize the study.
11. Pregnant/ lactating females.
12. Patients on oral contraceptives.
13. Alcoholics and/or drug abusers.
14. H/o hypersensitivity to any of the trial drugs or their ingredients.
15. Patients who have completed participation in any other clinical trial during the past six (06) months.

Any other condition which the Principal Investigator thinks may jeopardize the study.

Special Investigation:

- Total lipid profile.

Study Design:

The patient selected in the clinical trial has been given the following Ayurvedic Formulations:

***Vyoshadi Guggulu*:** [6]

Dose	1 gm (2 Tablets of 500mg each) thrice daily
Dosage form	Tablet of 500 mg
Route of Administration	Oral
Time of Administration	Thrice a day after food
Anupana	Lukewarm Water
Packing form	Bottle 30 gm (60 tablets of 500 mg each)
Duration of therapy	12 weeks

***Haritaki* Churna:** [7]

Dose	3 gm twice daily
Dosage form	Powder
Route of Administration	Oral
Time of Administration	Twice a day after food
Anupana	Lukewarm Water
Packing form	Plastic Jar of 90 gm (30 sachets of 3 gm each)
Duration of therapy	12 weeks

Assessment Criteria

Assessment of the patients was done on the subjective & objective parameters. Visual analogue Scale Score of the subjective criteria recorded to assess any changes present in the patients.

Statistical Analysis

The information gathered on the basis of above observations was subjected to statistical analysis.

Students' paired 't' test was applied for the objective parameters like haematological investigations to analyze the effect of individual therapy in the group. 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 $P < 0.05$, Significant $P < 0.01$, Highly Significant $P < 0.001$.

The Wilcoxon's Signed-Rank Test was carried out for all non-parametric data (i.e. for subjective criteria) to analyze the effect of individual therapy in group. The obtained results were interpreted as, Insignificant $P > 0.05$, Significant $P < 0.05$, Highly Significant $P < 0.01$.

OBSERVATIONS AND RESULTS

Among observations it was found that, Maximum patients i.e. 45.28% were from the age group of 30-50 years, 52.83% were females and 86.79% were *Hindu* while 96.23% patients were literate. Socio-economic status wise maximum 90.57% patients were from above poverty line, Maximum i.e. 45.28% patients were housewives, 86.79% patients were married, 84.91% patients were from urban habitat. 56.60% of the patients were of *Pitta- Kapha Prakriti*, 30.19% patients were having weight in the category of 70-80 kg & 60-70 kg each. 81.13% patients were having *Madhyama Ahara Shakti*. Maximum i.e. 56.60% patients were reported to have *Guru Ahara Sevana* followed by, 37.74% & 32.08% patient having *Akala* & *Atisnigdhahara Ahara Sevana*. Maximum i.e. 64.15% patients were found to have day sleep. In *Manasika Nidanas*, Maximum 11.32% patients were found to have *Atichinta*, *Beejadosha* was reported in 16.98% of patients, 43.40% of the patients which were having *Medovaha Srotodushti*.

Effect of therapy:

50% decrease in the breathlessness (**Table 1**), 60.47% difference seen in the parasthesia (**Table 2**), 83.12% improvement seen in the confusion (**Table 3**), 94.40% improvement in the fatigue (**Table 4**) was seen. On statistical analysis the result were found highly significant ($p<0.01$).

In patients treated with *Vyoshadi Guggulu* and *Haritaki Churna* there was a decrease of about 0.93%, 16.60%, and 0.39% in S.Cholesterol, S. Triglyceride, S. LDL (**Table 5**) respectively. However, S. VLDL was found to be increased by 26.03%. Also S. HDL was increased by 0.09%. All these changes were statistically insignificant.

Table 1: Effect of Therapy on Breathlessness

Mean B.T	Mean A.T	Mean Diff.	%	'W'	'N'	'P'
22.34	11.17	11.17	50↓	210	20	<0.01

Table 2: Effect of Therapy on Paraesthesia

Mean B.T	Mean A.T	Mean Diff.	%	'W'	'N'	'P'
22.87	9.04	13.83	60.47↓	210	20	<0.01

Table 3: Effect of Therapy on Confusion

Mean B.T	Mean A.T	Mean Diff.	%	'W'	'N'	'P'
3.26	0.53	2.71	83.12883	15	5	<0.01

Table 4: Effect of Therapy on Fatigue

Mean B.T	Mean A.T	Mean Diff.	%	'W'	'N'	'P'
19.57	1.06	18.47	94.40	435.00	29.00	<0.01

Table 5: Effect of Therapy on Lipidprofile

Investigation (n= 47)	Mean		Mean Diff.	% change	S.D.±	S.E.±	't'	P
	B.T	A.T						
S. Cholesterol	212.30	210.31	1.97↓	0.93	33.45	4.87	0.40	>0.05
S.Triglycerides	210.38	193.79	16.60↓	7.89	83.21	12.14	1.37	>0.05
S. HDL	40.02	40.11	-0.09↑	0.21	8.44	1.23	0.00	>0.05

S. LDL	129.82	129.43	0.39↓	0.3	27.08	3.95	0.1	>0.05
S. VLDL	42.56	53.64	-11.08↑	26.03	106.91	15.59	0.71	>0.05

Table 6: Effect of Therapy on HbA1c

Investigation	Mean		Mean Diff.	% change	S.D. ±	S.E. ±	't'	P
n=47	B.T	A.T						
HbA1c	5.58	5.33	0.25	4.43↓	0.47	0.07	3.62	<0.01

DISCUSSION

There was a decrease of about 0.93%, 16.60%, & 0.39% in S.Cholesterol, S. Triglyceride, S. LDL respectively in patients treated with *Vyoshadi Guggulu & Haritaki Churna*. However, S. VLDL was found to be increased by 26.03%. Also S. HDL was increased by 0.09%. All these changes were statistically insignificant. Mostly combination of *Katu-Ras, Laghu, Ruksha Guna and Ushna-Virya, Katu-Vipaka Pradhana* drugs in *Vyosadi Guggulu* having all the properties and with the help of *Laghu, Ruksha Guna Pradhan* and *Ushna Virya Haritaki* this drugs can do the function of *Strotoshodhana* and *Kapha, Kleda* and *Meda hara karma.* These drugs may be effective on *Rasa, Meda, Medodhatvagni*, which may be provided good results.

HbA1c found to be decrease by 4.43% which is statistically significant ($p<0.01$). In general, the higher HbA1c creates the higher risk for development of conditions such as Eye disease, Heart disease, Kidney disease, Nerve damage & Stroke.[8] Thus considering HbA1c as marker for development of risk in above mentioned conditions the trial drugs may be considered effective in preventing and managing these disorders

CONCLUSION

- Day sleep and Dietary mishaps like heavy to digest diet, irregular diet adds potently to the *Samprapti* of the dyslipidemia due formation of *Ama* and over increase in *Snigdha Guna* impairing the metabolic equilibrium of the body.
- Clinically in patients treated with *Vyoshadi Guggulu* and *Haritaki Churna* there was a decrease in S. Cholesterol, S. LDL and S. Triglyceride but not up to the significant extent.
- *Vyoshadi Guggulu* and *Haritaki Churna* was found to be very well effective in reducing the symptoms of *Medodushti* like breathlessness, confusion, paraesthesia and fatigue.
- Symptomatic relief suggests the effect of drug under trial on the *Sthayi Medodhatu* as all the symptoms were associated to the greater extent with excess fatty deposition in the body.
- Thus, *Vyoshadi Guggulu* and *Haritaki Churna* though effective to a lesser extent on reducing Lipid profile but it can be used for effective management of all other subjective parameters.

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