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Research Article

AYURVEDIC MANAGEMENT OF DYSLIPIDEMIA W.S.R TO *MEDO ROGA*: A CLINICAL TRIAL

Vijay Chaudhary[1]*, Suraj Negi[2], Minakshi[3], Sameet Masand[4]

*[1]Professor, [2]Research Scholar, [3]Senior lecturer, P.G.Department of Kaumarbhritya, R.G.G.P.G. Ayurveda College, Paprola, Himachal Pradesh, India.

[4]Assistant Professor, P.G.Department of Rasashastra evum Bhaishajya Kalpana, V.Y.D.S. Ayurved Mahavidyalya, Khurja, Uttar Pradesh, India.

KEYWORDS: *Medoroga*, Obesity, Dyslipidemia, *Dashang Guggulu*, *Triphaladi Kwatha*, Atorvastation.

***Address for correspondence**
Dr. Vijay Chaudhary
Professor,
P.G. Department of Kayachikitsa,
R.G.G.P.G. Ayurveda College,
Paprola, Himachal Pradesh.
Email:
drvijaychaudhary@gmail.com
Contact number: 9418130228

ABSTRACT

Obesity is one of the most common disorders of present era giving rise many serious consequences. Excessive intake of food along with stress, lack of exercise, and excess of junk food, canned food, soft drinks, beverages, food containing excessive fat and calories leads to obesity and coronary artery disease. In the present study comparative efficacy of Ayurvedic formulation (*Dashang gugglu* with *Triphaladi Kwatha*) was evaluated in a clinical trial to a standard drug i.e., atorvastatin on patients of *Medoroga* and dyslipidemia. Total 30 patients of obesity and dyslipidemia were registered for the present study and were equally divided in two trial groups. Group I patients were administered with *Dashang Guggulu* with *Triphaladi Kwatha* whereas Group II patients were given atorvastatin as control group for a duration of 60 days. Patients were thoroughly assessed on various scientific parameters during complete trial period. The trial drugs showed promising results on dyslipidemia as well as on obesity (reduction of weight). Group I shows promising results in reducing body weight, BMI, skin fold thickness and clinical features however Group II i.e., control group proves to be much effective in improving deranged serum lipid levels. In Group I the mean score of serum cholesterol was 231.41mg/dl which was reduced to 189.08mg/dl with 18.29% reduction. In Group II average value for serum cholesterol was 210.53mg/dl which was reduced to 162.92mg/dl with 22.62% reduction. Group I patients shows 5.60% reduction in BMI while Group II patients shows 2.15% change which means Ayurveda formulation is much more effective than atrovastatin in reducing BMI however difference in two therapies was statistically insignificant. These results prove the efficacy of Ayurvedic formulation in the management of *Medoroga*.

INTRODUCTION

Obesity is recognized as a major health problem in both developed as well as developing countries. It has been considered as one of the major risk factors for many other chronic diseases like diabetes, coronary artery disease etc. Today's erroneous life style is primarily responsible for increasing incidence of this disease in the society. Majority of the population in the society is now inclined towards junk food which contains lot of fats. Physical activity is decreasing day by day which results in fat storage leading to obesity and related disorders. Obesity was an uncommon disorder in the previous centauries. In 1997 WHO (World Health Organization) formally recognized obesity as a global epidemic. In year 2008 WHO claimed 1.5 billion adults of 20 and older were overweight and of those 200 million men and 300 million women were obese. Incidence of obesity in India is also rising with morbid obesity affecting 5% of countries population. In Ayurveda, *Medoroga*[1]

has been described in different texts in an elaborate manner covering its etiology, clinical features, complications, prognosis and management [2]. Acharya Charaka has described this clinical condition as one among the *Ashtanindita purusha*[3] (eight despicable persons). While Acharya Sushruta considers *Sthoola*[4] as *Sadatura* because *Sthaulya* is making the victim prone for so many other diseases. The Ayurvedic fundamental principle of *Samanya* and *Visesha*[5-6] is very essential for the understanding the state of health and diseases and the same can be applied for management of *Medoroga*. Most of the drugs used in modern era to manage obesity are associated with serious untoward effects and when these medicines are withdrawn a profound rebound weight gain is observed. Considering these facts, medical fraternity is always looking for safe and effective therapy for managing this notorious disease. Many studies were conducted in obesity like effect of *Gomutra* and *Haritaki* in controlling *Sthaulya* etc., considering all these studies and facts, the two compound herbal formulations have been selected for the present study on the basis of textual indications and clinical experience. *Dashang Guggulu* is one of the important *Guggulu* preparation used for *Medoroga* (obesity)[7]. As per *Bhavprakasha*, *Dashanga Guggulu* act therapeutically on *Kapha* and *Medovikara*. It also works in *Amajvikara* like *Amavata* also[8]. *Triphala* is used as *Anupana* with *Dashang Guggulu* as it is *Ruksha*, *Agnideepak* and *Kaphanashak*, so it is helpful in *Medoroga*.

MATERIALS AND METHODS

Selection of the Patients

A total of 30 patients were selected from the present study from O.P.D. and I.P.D. of Kayachikitsa department of R.G.G.P.G. Ayurvedic College Hospital, Paprola irrespective of their gender, caste and socio economic status etc.

Criteria for Diagnosis

1. Subjective Criteria- Classical signs and symptoms of *Medoroga* mentioned in Ayurvedic and modern texts. Table No. 1
2. Objective Criteria Table no. 2

Inclusion Criteria

1. Patients willing to participate in the trial
2. Age between 18 – 70 years.
3. Only uncomplicated cases of *Medoroga*.
4. Body mass Index (BMI) > 25
5. Deranged lipid profile

S. Cholesterol	> 200 mg/ dl
STG	>150 mg/dl
LDL	> 100 mg/dl
VLDL	> 40 mg/dl
HDL	< 40 mg/dl

Exclusion Criteria

1. Patients not willing for the trial.
2. All *Medo Rogi* presenting with complication like *Prameha Pidika*.
3. Drug induced obesity.
4. Obesity due to endocrine disorders.

Laboratory Investigations - Hb gm %, TLC, DLC, ESR, FBS, Blood urea, Serum creatinine, SGOT, SGPT, Urine - Routine and microscopic

Method of study

Trial Group - Total 30 patients of *Medoroga* were selected for the present clinical study, they were randomly divided and managed into following two groups:

1. **Trial group:** Total 15 patients were registered in trial group and out of them 3 patients discontinued the treatment and only 12 patients completed the study. The selected patients were given the trial drugs i.e., *Dashang Guggul* in the dose of 1.5g thrice a day and *Triphaladi Kwatha* in the dose of 50ml twice a day after meals.
2. **Control group:** Total 15 patients were registered in control group and out of them 2 patients discontinued the treatment and only 13 patients completed the study. These patients were given tablet atorvastatin 10mg once a day.

Duration of trial: Duration of trial was 60 days

Patients were advised to visit for follow-up after every 15 days or as per requirement. Patients were explained the possible benefits of trial and strictly advised to not to discontinue the trial drug till the trial was over. They were advised not to take any medications during the trial period. Patients were advised to crush the pills of *Dashang Guggulu* before swallowing. Patients were told to follow the *Pathya- Apathya*, *Ahara* and *Vihara* according to Ayurvedic principles. They were advised to take plenty of green leafy vegetable and to avoid high calorie food and overall assessment was done by grading method. (Table no. 3)

RESULTS

All registered patients were assessed thoroughly after every 15 days for the effect of therapy on the basis of various subjective and objective criteria. Biochemical tests were also performed before starting and after completion of trial. Effects of therapy on various subjective and objective parameters are shown in Table No.4, Table No. 5, Table No. 6 and Table No.7. The overall effect of two trial drugs was evaluated on the basis

of various subjective and objective criteria selected for assessment of results. The patients were categorized into markedly improved, moderately improved, mildly improved and unchanged according to assessment criteria. (Table No.8)

DISCUSSION

The main improvement in symptoms i.e., *Kshudra Shwasa*, *Pipasa Atiyoga*, *Swedabadha*, *Sandhi Shool*, *Daurgandhya*, *Daurbalya*, *Kshudha Atimatra*, *Chala Sphika Udara Stanam*, *Javoprodha* in trial group was 51.19% and in control group it was 17.35%. The improvement was highly significant ($p<0.001$) on *Daurbalya* and *Sandhi Shool* whereas in rest of symptoms i.e. *Kshudra Shwasa*, *Pipasa Atiyoga, Swedabadha, Daurgandh, Kshudha Atimatra, Chala Sphika Udara Stanam, Javoprodha,* effect of therapy was statistically significant ($p<0.05$) in trial group. In control group improvement was insignificant ($p>0.05$) on all the symptoms except on *Daurbalya*. Inter group difference on *Kshudra Shwasa, Pipasa Atiyoga, Swedabadha, Sandhi Shool,* and *Daurgandhya* was significant ($p<0.05$) and on rest of symptoms i.e. *Daurbalya, Kshudha Atimatra, Chala Sphika Udara Stanam, Javoprodha*, it was insignificant ($p>0.05$)

Reduction in BMI in trial group was 5.60%. In control group it was 2.15%. *Dashang Guggulu* with *Triphaladi Kwatha* proved more effective in reducing BMI than control group drug i.e. atorvastatin however difference in two therapies was statistically insignificant ($p>0.05$).

In trial group the mean score of serum cholesterol was 231.41mg/dl which was reduced to 189.08mg/dl with 18.29% reduction. In control group average value for serum cholesterol was 210.53mg/dl which was reduced to 162.92mg/dl with 22.62% reduction. Therapy given in control group i.e., Atorvastatin proved more effective in reducing S. Cholesterol. Difference in the effect of both the therapies was statistically significant ($p<0.05$). In trial group average value for serum triglyceride was 191.66mg/dl which was reduced to 146.00mg/dl with 23.82% reduction. In control group average value for serum triglyceride was 199.38mg/dl which was reduced to 127.77mg/dl with 35.92% reduction. Difference in the effect of both the therapies was significant ($p<0.05$). In trial group average value for serum LDL was 148.50mg/dl which was reduced to 120.75mg/dl with 18.69% reduction. In control group average value for serum LDL was 174.77mg/dl which was reduced to 109.61mg/dl with 37.28% reduction. Difference in the effect of both the therapies was insignificant ($p>0.05$). In trial group average value for serum VLDL was 37.75mg/dl which was reduced to 29.33mg/dl with 22.29% reduction. In control group average value for serum VLDL was 40.69mg/dl which was reduced to 26.69mg/dl with 34.40% reduction. Difference in the effect of both the therapies was insignificant ($p>0.05$). In trial group the average value for serum HDL was 45.17mg/dl which was increased to 48mg/dl with 11.77% increase. In control group average value for serum HDL was 30.53mg/dl which was increased to 40.38mg/dl with 32.26% increase. Difference in the effect of both the therapies was insignificant ($p>0.05$).

Overall effect of therapy showed that out of 12 patients in trial group 16.66% patients (02) showed marked improvement, 58.33% patients (7) were moderately improved and 25% patients (03) were mildly improved. In control group out of 13 patients 07.69% (01) showed marked improvement, 15.38% patients (2) showed moderate improvement and 76.92% patients (10) were mildly improved. Most of the routine haematological and biochemical investigations remained within normal limits in both the groups before and after the therapy.

The components of *Dashang Guggulu* [Purified *Guggulu* (*Commiphora mukul*), *Haritaki* (*Terminalia chebula*), *Bibhitaki* (*Terminalia bellirica*), *Amalaki* (*Emblica officinalis*), *Pippali* (*Piper longum*), *Marich* (*Piper nigrum*), *Sunthi* (*Zingiber officinale*), *Chitrakmool* (*Plumbago zeylanica*), *Musta* (*Cyperus rotundus*) and Vidang (*Embelia ribes*)] with *Triphaladi Kwatha* [*Amla* (*Emblica officinalis*), *Haritaki* (*Terminalia chebula*) and *Vibhitaki* (*Terminalia bellirica*)] are *Deepan*, *Pachan, Kapha – Vatahara* and *Srotoshodhak* as most of the drugs have *Katu Tikta Rasa*, *Laghu*, *Ruksha, Tikshana, Guna, Ushana, Virya* and *Katu Vipaka* so effectively interrupt the *Samprapti* of *Medo Roga* at various levels.

Guggulu is responsible for reducing fat, indicated for healing bone fracture to inflammation, arthritis, atherosclerosis, obesity, and hyperlipidemia[9]. Guggulipid is a standardized extract prepared from the oleogum resin (gum resin) of *Commiphora mukul*, commonly known as *Guggul* belonging to the family Burseraceae, is indigenous to India and is also found in Bangladesh and Pakistan. It grows wild in the semi-arid states of Rajasthan, Gujarat, and Karnataka in India. As afore mentioned, GL has been safely used for thousands of years in the Indian Ayurvedic medicine for the treatment of different ailments, including lipid disorders, rheumatoid arthritis, ulcers, osteoarthritis, bone fractures, epilepsy, and obesity[10,11]. In 1986, GL was granted approval in

India for marketing as a lipid lowering drug[12]. Several products of standardized formulations of *Commiphora mukul* are already in human use as cholesterol-lowering agents. The Z- and E-forms of guggulsterone (Gug, 4, 17(20)-pregnadie-3, 16-dione) have been identified as major active components of GL[10,13]. GL and its active component z-Gug have been used in many clinical trials that focused on its cholesterol-lowering effect. *Commiphora mukul* has been clinically proven to reduce the levels of harmful serum lipids in the blood stream. The active ingredients responsible for the maintenance of healthy cholesterol levels are the guggulsterones, specifically guggulsterone E and guggulsterone-Z [14,15].

The hypolipidemic activity of *Guggulu* could be attributed to the following possible mechanisms includes: [16]

- ✓ Inhibition of cholesterol biosynthesis
- ✓ Enhancing the rate of excretion of cholesterol
- ✓ Promoting rapid degradation of cholesterol
- ✓ Thyroid stimulation
- ✓ Alteration of biogenic amines, High-affinity binding and anion exchange.

The first three mechanisms, inhibition of cholesterol biosynthesis, enhancing the rate of excretion of cholesterol and promoting rapid degradation of cholesterol are related in that the end result is the elimination of cholesterol. *Guggulu* compounds are antagonist ligands for bile acid receptor called farnesoid X receptor (FXR), which is an important regulator of cholesterol homeostasis. It is likely that this effect accounts for the hypolipidemic activity of these phytosterols. Guggulsterone has the capability of inhibiting oxidative modification of LDL. While Guggulsterone E (GSE) or Z (GSZ) had no effect on FXR activity per se, both compounds statistically and dose dependently inhibited FXR activation by chenodeoxycholic acid, the most potent of the bile acids activating FXR. This may imply that guggulsterones enhance conversion of cholesterol into bile acids which could be excreted in the feces lowering the liver and body cholesterol level[17, 18].

Other drugs such as *Triphala*,[19] *Pippali*,[20] *Shunthi*,[21] *Musta*,[22] *Chitraka*,[23] and *Vidanga*[24] have also proven lipid lowering activity. Thus, the whole composition exhibited antihyperlipidemic effect.

CONCLUSION

The trial drugs showed promising results on obesity as well as on dyslipidemia. Body weight, BMI and serum lipids were also reduced significantly. Trial drugs i.e. *Dashang Guggulu* with *Triphaladi Kwatha* were found more effective in reducing body weight, BMI, skin fold thickness and clinical features however modern drug i.e. atorvastatin proved more effective in improving deranged serum lipid levels. Trial drugs have no untoward effects so can be used for a long duration. Thus it can be concluded that *Dashang Guggulu* with *Triphaladi Kwatha* have beneficial effect in patients of *Medoroga* and dyslipidemia but as the present study has been conducted on small sample size further multi centre and double blind studies on larger samples size needs to be done to confirm the effectiveness and safety of the drug.

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Table 1: Subjective criteria were given grades according to severity of symptoms.

S. no.	Symptom	Grading
1.	*Kshudra Shawasa* (Shortness of breath)	No shortness of breath - 0 Slight shortness of breath after hard physical work – 1 Shortness of breath after mild physical exercise - 2 Shortness of breath even at rest - 3
2.	*Sandhi Shoola* (Pain in joints)	No pain - 0 Mild pain of low intensity causing no disturbance in routine work - 1 Moderate pain hampering daily routine work - 2 Severe pain causing definite interruption in routine work -3
3.	*Pipasa Atiyoga* (Excessive thirst)	< 1.5 Lit./ day of fluid - 0 1.5 – 2 Lit./ day of fluid - 1 2 – 3 Lit./ day of fluid - 2 >3 Lit./ day of fluid – 3

4.	*Kshuda Atimatra* (Excessive hunger)	< 2 chapattis / meal – 0 2 – 4 chapattis/ meal - 1 4 – 6 chapattis/ meal - 2 >6 chapattis/ meal - 3
5.	*Javaparodha* (Lassitude)	Fully active – 0 Hesitate to start work but once started, complete it - 1 Start but does not complete - 2 Doesn't have drive, work under compulsion - 3
6.	*Swedabadha* (Excessive sweating)	Normal perspiration – 0 Mild perspiration after doing exertion - 1 Heavy perspiration after doing little exertion - 2 Perspiration without exertion – 3
7.	*Nidradhikya* (Excessive sleep)	6 – 8 hrs/ day sleep – 0 8 – 10 hrs/ day sleep - 1 10 – 12 hrs/ day sleep - 2 12 – 14 hrs/ day sleep – 3
8.	*Chal Sphik Udra Stanan* (Movement of body parts)	Absence of movements – 0 Little movement after fast activity - 1 Movements after mild activity - 2 Movements even on changing posture – 3
9.	*Daurbalya* (Weakness)	No tiredness – 0 Mild fatigue after doing work - 1 Tired after doing work - 2 Works with great difficulty – 3
10.	*Daurgandhya* (Bad odour)	Absence of odour – 0 Occasional bad odour - 1 Persistent bad odour - 2 Persistent bad odour intolerable to patient – 3

Table 2: Objective criteria were given grades according to normal standards

S.no.	Criteria	
1.	Raised Body height- weight Ratio:	BMI = Weight (kg)/Height(M)^2 > 25
2.	Body weight	➢ Reduction of >4 kg of body weight. ➢ Reduction of 2 – 4 kg of weight. ➢ Reduction of 1 – 2 kg of weight
3.	Lipid profile	S. Cholesterol > 200 mg/dl S. Triglycerides > 160 mg/dl S. LDL > 160 mg/dl S. VLDL > 30 mg/dl S. HDL < 30 mg/dl

Table 3: Overall assessment criteria

S. no.	Improvement criteria	Grading
1.	➢ >60% Reduction in subjective symptoms. ➢ Reduction of >4 kg of body weight. ➢ Reduction of > 2 grades of BMI ➢ More than30% reduction in two or more than two factors out of S.	Markedly improved

	Cholesterol, triglycerides, LDL, VLDL. ➢ More than30% elevation in HDL.	
2.	➢ > 30% Reduction in subjective symptoms. ➢ Reduction of 2 – 4 kg of weight. ➢ Reduction of one grade in BMI. ➢ 15-30% reduction in two or more than two factors out of S. Cholesterol, Triglycerides, LDL, VLDL. ➢ 15-30% elevation in HDL.	Moderately improved
3.	➢ < 30% Reduction in subjective symptoms - Reduction of 1 – 2 kg of weight - Reduction of one grade in BMI. - Upto 15% reduction in one factor out of S. Cholesterol, triglycerides, LDL, VLDL - Upto 15% elevation in HDL.	Mildly improved

Table 4: Comparative effect of *Dashang Guggulu* with *Triphaladi Kwatha* and Atorvastatin on clinical features

Clinical features	Trial group					Control Group					I v/s II t	P
	Mean score		% age Reduction	SD±	T	Mean score		% age Reduction	SD±	T		
	BT	AT				BT	AT					
Kshudra Shwasa	1.67	1.08	35.0	0.66	3.02	1.67	1.50	15.0	0.38	1.48	2.42	<0.05
Pippasa Ati Yoga	1.33	0.33	75.0	0.63	3.87	1.60	1.20	25.0	0.55	1.63	2.98	<0.05
Swedabadha	1.09	0.45	58.33	0.50	4.18	1.50	1.25	16.66	0.46	1.53	2.26	<0.05
Nidradhikya	1.14	0.42	62.5	0.48	3.87	1.42	1.14	20.0	0.49	1.55	1.81	>0.05
Daurbalya	1.83	0.91	50.0	0.51	6.16	1.50	1.16	22.22	0.49	2.34	1.12	>0.05
Kshudha Atimatra	2.18	1.36	34.78	0.60	4.50	1.73	1.45	15.78	0.47	1.94	0.46	>0.05
Chal Sphik Udar Stan	1.63	1.00	38.88	0.50	4.18	1.58	1.33	15.78	0.45	1.91	1.44	>0.05
Sandhi Shool	1.60	0.70	56.25	0.31	9.00	1.83	1.50	18.18	0.52	1.16	2.58	<0.05
Javuprodha	1.54	0.90	41.17	0.50	4.18	1.54	1.27	17.64	0.47	1.93	1.14	>0.05
Daurgandhya	1.11	0.44	60.00	0.50	0.40	1.30	1.00	23.07	0.48	1.96	3.29	<0.05

Table 5: Comparative effect of *Dashang Guggulu* with *Triphaladi Kwatha* and Atorvastatin on body weight

Criteria	Trial group					Control Group					I vs II t	P
Body weight	Mean weight		% age reduction	SD	T	Mean weight		% age reduction	SD	T		
	BT	AT				BT	AT					
Weight (kg)	80.0	75.66	5.42	1.30	11.52	78.08	76.61	0.88	1.05	5.02	0.20	>0.05

Table 6: Comparative effect of *Dashang Guggulu* with *Triphaladi Kwatha* and atorvastatin on BMI

Criteria	Trial group					Control Group						
	Mean value		%age reduction	SD	T	Mean value		% age reduction	SD	t	I v/s II t	P
	BT	AT				BT	AT					
BMI	31.73	29.27	5.60	0.48	13.29	31.53	30.80	2.15	0.39	6.59	0.48	>0.05

Table 7: Comparative effect of *Dashang Guggulu* with *Triphaladi Kwatha* and atorvastatin on Lipid profile

Variable	Trial group					Control Group					I vs II t	P
	Mean value		% age change	SD	T	Mean value		%age change	SD	T		
	BT	AT				BT	AT					
S. cholesterol	231.41	189.1	18.29	17.4	8.4	210.5	162.9	22.62	26.5	6.49	2.33	<0.05
S. Triglyceride	191.6	146.0	23.82	33.9	4.6	199.4	127.8	35.92	19.8	13.0	2.96	<0.05
S. LDL	148.5	120.7	18.69	19.5	4.9	174.8	109.6	37.28	22.6	10.4	1.06	>0.05
S. HDL	45.2	48.0	11.77	6.44	2.5	30.5	40.38	32.26	6.9	5.12	1.97	>0.05
S. VLDL	37.7	29.3	22.29	07.2	4.0	40.7	26.7	34.40	5.4	9.37	1.96	>0.05

Table 8: Overall effect of therapy in trial group and control group

Result	Trial Group		Control Group		Total	
	No. of patients	% age	No. of patients	% age	No. of patients	% age
Markedly improved	02	16.66	01	07.69	03	12.17
Moderately improved	07	58.33	02	15.38	09	36.85
Mildly improved	03	25.00	10	76.92	13	50.96
No improvement	00	00.00	00	00.00	00	00.00

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