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CLINICAL EVALUATION OF *TAMRA BHASMA* WITH *AMRITADYA GUGGULU* IN THE MANAGEMENT OF *MEDO ROGA* W.S.R.TO DYSLIPIDAEMIA

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ABSTRACT

The primary aim of *Ayurveda* is to cure the disease and to maintain health state. *Medo Roga* is a metabolic disorder which is very frequently encountered in routine clinical practice nowadays. In modern era with continuous changing life styles, faulty dietary habits and with some environmental factors man has become victim of many diseases including *MedoRoga*. *MedoRoga* is described in different classical texts. *Acharya Charaka* has described the disease in *Ashtonindatiya Adhyaya*. *Acharya Charaka* has explained the disease as *Ati-sthoola* under *Niniditapurusha* concept. *Ati-sthool* is a person in whom excessive and abnormal increase of *Medodhatu* along with *Mansa dhatu*, result in pendulous appearance of buttocks, abdomen and breast. This condition is presently described as obesity. This obesity presents itself as weight gain, increased B.M.I. and very commonly occurred altered lipid profile i.e. dyslipidemia. *Medo Roga* further leads to many disease conditions like Diabetes Mallitus, Hypertension etc. It is thus a serious public health problem. Metallic *Bhasmas* are highly valued in *Ayurvedic* treatment as they have good preventive, curative and rejuvenating potential due to its rapid dissolution, quick bioavailability, low dose requirement and easy palatability. Keeping in view this burning problem of present era and its associated devastating effects, the present research work has been chosen. *Amritadya Guggulu* has been advocated in *sthaulya* like

condition and described as *lekhana* in our classical texts. Though nowadays it has been observed that dyslipidemia is also sometimes presents in non-obese subjects but considering common criteria in obese, this quantitative criterion has been selected. The proposed work was on 10 patients under open uncontrolled single group with *Tamra Bhasma* 60 mg as capsule & *Amritadya Guggulu* 500 mg in powder form (to be dispensed as capsule) with Luke warm water twice a day for 30 days. Follow up of the patients was on 15th day and after completion of the clinical trial.

KEYWORDS: *Medo Roga, Amritadya Guggulu*, Dyslipidemia, *Tamra Bhasma*.

INTRODUCTION

Rasa Shastra is one of the flourish subject of *Ayurveda* as well as backbone of the treatment. *Rasa Shastra* is the branch of *Ayurveda*, which deals with different types of *kalpanas* like *Bhasma, Pishti, Pottali, Kupi-pakwa* etc. Almost all the substances used in *Rasashastra* i.e. minerals, metals or herbal poisonous substances etc. need to be transformed to make them human friendly, pharmaco-therapeutically useful and safe. Here comes the significance of *Shodhana, Marana, Jarana* and many other processes which transform these substances into non-toxic, disease eliminating, preventing and health promoting i.e. most effective remedies of *Ayurveda.*

Medo Roga is a metabolic disorder which is very frequently encountered in routine clinical practice nowadays. In modern era with continuous changing life styles, faulty dietary habits and with some environmental factors man has become victim of many diseases including *Medo Roga*. *Medo Roga* is described in different classical texts. *Acharya Charaka* has described the disease in *Ashtonindatiya Adhyaya*. *Acharya Charaka* has explained the disease as *Ati-sthoola* under *Ashtaninditapurusha* concept. *Ati-sthoola*[1] is a person in whom excessive and abnormal increase of *Medodhatu* along with *Mansa dhatu*, results in pendulous appearance of buttocks, abdomen and breast. This condition is presently described as obesity. This obesity presents itself as weight gain, incresed B.M.I. and very commonly occurred altered lipid profile i.e. dyslipidemia. *Medo Roga* further leads to many disease conditions like Diabetes Mallitus, Hypertension etc. Raised cholesterol increases the risks of heart disease and stroke.

WHO data shows high cholesterol level attributes ischaemic heart disease which is 3rd major cause of death worldwide. Raised cholesterol is estimated to cause 2.6 million deaths (4.5%

of total) and 29.7 million disability adjusted life years (DALYS), or 2.0% of total DALYS. In 2008 the global prevalence of raised total cholesterol among adults (≥ 5.0 mmol/l) was 39% (37% for males and 40% for females). Globally, mean total cholesterol changed little between 1980 and 2008, falling by less than 0.1 m mol/L per decade in men and women. The prevalence of elevated total cholesterol was highest in the WHO Region of Europe (54% for both sexes), followed by the WHO Region of the Americas (48% for both sexes). The WHO African Region and the WHO South East Asian Region showed the lowest percentages (22.6% for AFR and 29.0% for SEAR).[2]

Metalic *Bhasma* are highly valued in *Ayurvedic* treatment as they have good preventive, curative and rejuvenating potential due to its rapid dissolution, quick bioavailability, low dose requirement and easy palatability.[3] keeping in view this burning problem of present era and its associated devastating effects, the present research work has been carried out.

Tamra Bhasma[4] and *Amritadya Gugggulu*[5]have been advocated in *sthaulya* because of *lekhana* and *sthaulyapaha* properties in our classical texts. *Tamra Bhasma* is having *ushna veerya* & *lekhana*[4] (scraping) properties and it is widely used in treatment of *Kushtha*, *Pandu*, *Sthaulya*, *Yakrit vikara*[6] etc.

Aim: In general clinical studies are designed to add medical knowledge related to the treatment, diagnoses and prevention of diseases. Aims of the studies are as follows.

- To review the *Ayurvedic* and modern literature related to *Medo Roga* and Dyslipidemia.
- To establish a safe and cost effective medicine for the treatment of *Medo Roga*.
- To study the other associated effects or adverse effects of the trial drugs if any.

STUDY DESIGN

MATERIAL AND METHOD

1. Protocol of Clinical Work

Selection of subject

A total no. of 10 volunteers/Patients attending the R. G. G. P. G. *Ayurvedic* College & Hospital, Paprola, Himachal Pradesh were selected in the age group of 25 years to 60 years irrespective of race, caste and religion. It was an open trial and patients were treated with *Tamra Bhasma* and *Amritadya Guggulu*. Written & informed consent of patients was taken before trial.

2. **Selection of Patient**

Inclusion Criteria

1. Patients willing for clinical trial and ready to give written consent.
2. Patients in the age group of 25 – 60 years of either sex.
3. Patients possessing signs and symptoms of *Medo Roga* on the basis of diagnostic criteria.
4. Patients having Body weight more than the standard weight for their height.
5. Patients with BMI >25 (in male) or >24 (in female).
6. Patient not having any associated chronic ailment.

Exclusion Criteria

1. Patients not willing for the clinical trial.
2. Patients not fulfilling the inclusion criteria.
3. Patients below the age of 25 years and above the age of 60 years.
4. Patients suffering from AIDS, cancer, tuberculosis, diabetes mellitus or any other severe systemic disorders.
5. Patients having hepato-renal disease, hypersensitivity were excluded.

Drug Review: *Bhasma* of *Tamra* was prepared after *shodhana* as per reference of *Ras Ratna Samucchya*.[6] *Amritadya Guggulu was prepared as per reference of Chakradatta having ingredients Tinospera cordifolia, Elettaria cardamomum, Embelia ribes, Holarrhena antidysenterica, Terminalia belerica, Emblica officinalis, Terminalia chebula and Commifora mukul*. Guggulu Shodhana[7] was done as per reference of AFI.

Study Procedure: At the randomized visit, a detailed history was obtained from all the enrolled patients. Subsequently, all the patients had undergone through systemic examination (History, body weight, B.M.I.), Blood investigations (Hb%, TLC, DLC, ESR, Fasting Blood Sugar, Lipid profile, Renal function Test).

Dose of Drug: *Tamra Bhasma*- 60 mg with *Amritadya Guggulu*-500 mg twice a day.
***Anupana*:** Luke warm water.
Duration of Trial: 30 days.

Monitoring & follow up: All the patients were monitored at 15 days interval for clinical assessment as per subjective and objective criteria. All the patients were undergone with biochemical investigation.

Subjective parameters- Dyspnoea *(Kshudra Shwasa)*, *thirst (Trishna)*, Sleep *(Nidra)*, Malaise *(Anga sada)*, Hunger *(Kshudha)*, Sweating *(Sweda)*, Foul smell of body *(Daurgandhya)* and Fat deposition on abdomen *(Meda on udara).*

Objective parameters- B.M.I.

Response to treatment was evaluated on a predefined symptom score scale from 0 to 4 (4 – maximum; 0- nil) for clinical features.

Assessment of effect of therapy: Patients were examined before and after the therapy for improvement in clinical symptoms, BMI and Laboratory parameters. Overall percentage improvement of each patient was calculated by the following formula.

$$\frac{BT - AT}{BT} \times 100$$

The result thus obtained from individual patient was categorized according to the following grades

1. No improvement in symptoms : 0 %
2. Mildly improvement in symptoms : 0% –30 %
3. Moderately improvement in symptoms : 31% – 60 %
4. Highly improvement in symptoms : 61% – 90 %
5. Complete remission of symptoms : 91% – 100 %

STATISTICAL ANALYSIS

Statistical analysis was done accordance to intent-to-treat principle. Baseline comparison for subjective and objective criteria was done by using.

Effects of therapy on signs & Symptoms

Symptoms	Mean Score		%relief	S.D. (±)	S.E.	't'	P
	BT	AT					
Kshudra Swasa	2.100	0.500	76.19%	0.699	0.221	7.236	<0.001
Trishna	0.700	0.700	0	0	0	0	1
Nidra	2.800	0.800	71.47%	1.155	0.365	5.477	<0.001
Anga Sada	3.000	0.400	86.10%	0.699	0.221	11.759	<0.001
Kshudha	2.600	1.600	38.10%	0.667	0.211	4.743	0.001
Sweda	2.900	0.990	68.96%	0.667	0.211	9.487	<0.001
Daurgandhya	0.700	0.600	14.28%	0.316	0.100	1	0.343
Meda on *Udara*	2.300	2.000	13.04%	0.483	0.153	1.964	0.081

Effect of Therapy on BMI

No. of Patients	Mean		% relief	S.D. (±)	S.E	't'	'p'
	BT	AT					
10	29.575	28.780	2.68	0.435	0.137	5.783	<0.001

Effect of therapy on lab. Investigations: In the present study, routine hematological investigations along with Lipid profile and renal function tests were performed for each patient before and after the trial. The changes observed in these parameters in all the 10 patients who completed the treatment for entire duration were recorded. The mean score for each diagnostic parameter was calculated. Then the percentage increase or decrease in the mean score before and after the trial was observed. The summary of mean score of all the haematological and bio-chemical investigations is presented in tabular form.

Parametres		Mean		% D	S.D. (±)	SEM	't'	'p'
		BT	AT					
Hb%		13.03	12.43	**4.60%**	1.031	0.326	1.841	0.099
TLC		6588.9	6933.3	**5.23%**	1.454	0.460	0.021	0.983
DLC	LYM	47.2	29.81	**36.8%**	8.447	0.270	1.176	0.270
	NEU	55.75	58.39	**4.73%**	6.644	2.101	1.257	0.241
	MIX	8.52	9.89	**16.0%**	1.031	0.326	1.841	0.099
ESR		19.20	11.40	**40.62%**	21.149	6.688	1.166	0.273
FBS		92.70	89.90	**3.02%**	19.083	6.035	0.464	0.654
Serum Cholesterol		227.2	175.1	**22.09%**	44.620	14.110	3.692	0.005
HDL		45.60	51.40	**12.71%**	5.051	1.597	3.631	0.005
LDL		109.6	95.0	**13.32%**	11.965	3.784	3.859	0.004
VLDL		52.0	35.60	**31.53%**	22.950	7.257	2.260	0.050
Serum Triglyceride		270.0	185.0	**31.48%**	81.854	25.884	3.284	0.009
Blood Urea		24.60	26.90	**9.34%**	1.031	0.326	1.841	0.099
Serum Creatinine		0.89	1.04	**16.85%**	0.201	0.063	2.355	0.043

- No considerable change in haematological investigations, Fasting Blood Sugar, Blood Urea and Serum Creatinine was noted as a result of the therapy.

Overall effect of the therapy in 10 patients of *Medo Roga*

Effect	No. of Patients	Percentage
No Improvement	0	0 %
Mild Improvement	1	10 %
Moderate Improvement	8	80 %
Highly Improvement	1	10 %
Complete Remission	0	0 %

Among all the 10 patients, 1 patient was mildly improved, 8 patients were moderately improved while 1 patient was highly improved.

DISSCUSSION

Medo Roga results due to *Shleshma Vardhaka Ahara* and *Vihara,* which causes production of *Ama Rasa* by suppressing *Jatharagni*. It further causes *Medo Dhatvagni Mandya,* resulting in production of *Ama Meda*. It leads to *Sroto-sanga* thereby accumulation of *Medo Dhatu* and *Margavrodha* of *Vayu*. Both these factors lead to clinical presentation of *Medo Roga*.

In the *Samprapti* of *Medo Roga*, *Kapha* is main *Dosha* and *Meda* is main *Dushya*, while *Agnimandya* takes place at *Medo Dhatvagni* level. So, the drug which have *Kapha* and *Medo Nashaka* property and have efficacy to correct the function of *Medo Dhatvagni* will give better result in the management of *Medo Roga.*

Fortunately, the drugs *Tamra Bhasma* and *Amritadya Guggulu* fulfill all these requirements. They help in *Samprapti Vighatana* of *Medo Roga* either by their *Rasa, Guna, Virya, Vipaka* or *Karma* by acting at different levels i.e. *Dosha, Dushya, Agni or Srotas* and decreases the symptoms of *Medo Roga*.

Ushna Virya and *Katu Vipaka* might have corrected *Kapha Dushti,* which is the main cause in *Samprapti* of *Medo Roga*. Along with this, the properties like *Katu Rasa, Laghu, Ruksha, Tikshna Guna,* pacify the *dushti* of *Medo dhatu* leading to its normal functioning. The *Ushna Virya* along with its *Deepana* property acts at the level of *Dhatvagni* which may attribute in *Aama pachana* and *Agni dushti,* which is also one of the prime etiological factor of *Medo Roga*. The pharmacological actions like *Medohara* and *Lekhana* may be helpful in reducing *Abaddha Meda* and also facilitating normalization of *Medo dhatu vriddhi*.

Probable Mode of action of *Tamra Bhasma* in *Medo Roga*: The drug *Tamra Bhasma* by virtue of its *Kasaya Rasa, Laghu and sara Guna, Ushna Veerya* and *Katu Vipaka* might have corrected the *Kapha Dushti,* which is the main cause in *Samprapti* of *Medo Roga*. Along with this, these all properties pacify *dushti* of *Medo dhatu* leading to their normal functioning. The *Ushna Virya* along with its *Deepana* property may attribute in *Aama pachana* and *Agni dushti,* which is also one of the prime etiological factor of *Medo Roga*. The pharmacological actions like *Medohara* and *Lekhana* may be helpful in reducing increased *Meda* and facilitating normalization of *Medo dhatu vriddhi*.

The mean score of *Kshudra shwasa* came down. Mean score before treatment was 2.100, which came down to 0.500 at end of the therapy with percentage relief of 76.19%. It might be

due to the fact that copper has been shown to be an important cofactor for certain enzymatic reaction specifically cross linking of elastin is inhibited by copper deficiency. This inhibition leads to weakened connective tissue and pathological changes in the lungs.[8] The mean score of HDL increased. Mean score before treatment was 45.6 mg/dl, which increased to 51.4 mg/dl at the end of therapy with percentage increase of 12.71%. It may be due to the fact that *Tamra Bhasma* is cardio-protective in nature.[9]

Probable Mode of action of *Amritadya Guggulu* in *Medo Roga*: According to *Acharya Chakkrapani, Amritadya Guggulu* is composed of *Trifala, Laghu ela, Vidanga, Kutaj, Guduchi and Guggulu.* Most likely properties of *Amritadya Guggulu* will be primarily governed by large quantity, *veerya* dominancy and other properties of *guggulu*. Other ingredients make this formulation specific for site and system. On the basis of *Rasa-panchaka*, the probable mode of action of *Amritadya Guggulu* in *Medo Roga* can be explained as.

1. At the Level of *Dosha:* *Amritadya Guggulu* has *Katu, Tikta, Kasaya Rasa, ushna veerya* predominantly which might have corrected the *Kapha-dushti* which is the main cause of *Medo Roga* by virtue of their *kapha-shamaka* properties.[10]

2. At the Level of *Dushya*: From the *Samprapti* of *Medo Roga*, it is clear that the main *Dushya* involved is *Medo Dhatu*. The combination shows dominance of *Katu, Tikta, kasaya Rasa, Laghu, Ruksha, Tikshna Guna* and *Ushna Virya.* These all properties pacify *Dushti* of *Medo Dhatu*. Thus, this combination may act on *Medo Roga*.

3. At the Level of *Agni:* By virtue of its properties, it might have stimulated the *Jatharagni* which will further stimulate the *Medo-dhatvagni*. *Medo dhatvagni* will do *pachana* of *sanchita medo dhatu* and will inhibit further *medo dhatu sanchaya*. This will correct the basic pathology of *Medo Roga*.[11]

4. At the Level of *Aama:* *Aama* means unripe and undigested *Anna Rasa*. *Ushna veerya and Deepana properties of Amritadya Guggulu* might have stopped the further *Aama* production and helped in breaking the basic pathology of *Medo Roga*.

5. At the Level of *Srotasa:* The disease exhibits *Sanga* type of *Sroto Dushti*. The combination by virtue of *Laghu Guna, Tikta Rasa* and *Ushna Virya* might have relieved the *Sanga* type of *Dushti* and broken the *Samprapti* of *Medo Roga*.

It is also supported by the same fact that

- Guggulusterone, the bioactive constituent of *guggulu* is having antihyperlipidemic property which might have lowered the increased lipid profile.[12]
- The other ingredient of *Amritadya guggulu* i.e. *Laghu ela (Elatteria cardemomum)* has significant result in decreasing the serum cholesterol and triglycerides and increasing the HDL level.[13]
- The hypolipidemic activity of *Triphala* in experimentally induced hypercholesteremic rats has been also proved.[14]
- Another study on *Guduchi (Tinospora cordifolia)* showed significant reduction in serum LDL and serum cholesterol level and significant increase in the serum HDL level.[15]

Overall Probable Mode of Action of Therapy in *Medo Roga*: In *Medo Roga, Kapha Dosha* is mainly involved. Both the drugs are *Kapha Shamaka* in nature. Hence both the drugs act synergistically in relieving the symotoms of *Medo Roga*. In *Ayurvedic texts*, it has been stated that drugs which possess *Tikta, Katu Rasa, Katu-Vipaka, Ushna Virya* and *Medohara* and *Lekhana* properties should be preferred for the treatment of *Medo Roga.*

Both the drugs possess the pharmacological properties as explained in our texts and have moderate effect on symptoms of *Medo Roga* and significant result on lipid profile which was noted by Biochemical Investigations of blood. Both the drugs have super-additive effect on *Medo Roga* symptomatically as well as biochemically. Thus both the drugs can effectively cause the *Samprapti Vighatana* of *Medo Roga.*

CONCLUSION

- *Tamra Bhasma* and *Amritadya Guggulu* control Dyslipidemia without any side effect. The effect of therapy on all the symptoms was highly significant except *Daurgandhya, Meda* on *udara* and *Trishna* which was insignificant.

Scope for further research work

- Comparative clinical studies may be conducted by preparing the *bhasma* with both the methods. By this one can compare efficacy of both samples.

➢ The present study requires to be conducted on larger samples size and for longer duration. As it was done over a smaller sample size and for a short period of time, many aspects of study might have been left out of consideration.

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