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A COMPARATIVE CLINICAL EVALUATION OF VANG BHASMA ALONE AND VANG BHASMA WITH NAVAKA GUGGULU IN THE MANAGEMENT OF MEDOROGA WITH SPECIAL REFERENCE TO DYSLIPIDEMIA

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ABSTRACT

Objective of the study was to evaluate therapeutic efficacy of Vang Bhasma alone in relief in symptoms of Medo Roga, to evaluate therapeutic efficacy of Vang Bhasma with Navaka Guggulu in relief in symptoms of Medo Roga and to compare effect of Vang Bhasma alone and Vang Bhasma with Navaka Guggulu in relief in symptoms of Medo Roga. Design: Open randomized comparative clinical study with pre and post test design. 20 patients were diagnosed as suffering from Medo Roga. Interventions: Patients selected were randomly divided into 2 groups of 10 patients each. Group- I: 10 patients were treated with Vang Bhasma for a period of 45 days. Group- II: 10 patients were treated with Vang Bhasma with Navaka Guggulu for 45 days. Main outcome measures: Subjective parameters- Kshudra swasa, Trishna, Nidra, Anga sada, Kshudha, Sweda, Daurgandhya and Meda on udara. Objective parameters- Body weight and Body mass index. Laboratory investigations- Serum cholesterol, HDL, LDL, VLDL, Serum Triglycerides. Results: There was marked relief in symptoms of Medo Roga in both groups of patients as evidenced by reduction in the mean score of various subjective and objective parameters. There was statistically highly significant result in most of the subjective parameters, but while comparing both the groups, there was insignificant difference in the results. Vang Bhasma alone and Vang Bhasma with Navaka Guggulu both therapeutic modules are effective in relieving symptoms of Medo Roga as evidenced by statistically significant reduction in the symptom score of various subjective and objective parameters.

Keywords: Vang Bhasma, Navaka Guggulu, Medo Roga, Body mass index, Cholesterol.

INTRODUCTION

In the present era of modernization, the use of latest technology by human in every lifestyle has brought about drastic changes in dietary habits, modes of lifestyles and various regimens of life. Most of the individuals are habituated to luxurious and comfortable lifestyle leading to various chronic and non-communicable diseases. Hypertension, Diabetes millets, Ischemic heart disease, Varicose veins and Atherosclerosis etc. are recognized as major non-communicable diseases; for which Medo Roga (Dyslipidemia) is traced to be a major risk factor. Medo Roga is the commonest nutritional disorder in affluent societies and mostly prevalent in developed countries.

Medo Roga is a disorder of Medovaha srotasa as per Ayurvedic concept characterized by deposition of Meda at the site of Sphika (buttocks), Udara (abdomen), Stana (breast) and all over body[1]. The associated symptoms like Kshudra swasa (dyspnoea), Trishna (thirst), Nidra (sleep), Anga sada (malaise), Kshudha (hunger), Sweda (sweating), Daurgandhya (foul smelling), Alpa prana (decreased immunity) and Alpa maithuna (decreased libido) etc. are also found in this condition[2]. As per modern concept, it can be correlated with Dyslipidemia. It is a disorder of lipoprotein metabolism, including lipoprotein overproduction or deficiency. It may be manifested by elevation of the total cholesterol, low-density lipoprotein (LDL) cholesterol and the triglyceride concentrations, and a decrease in high-density lipoprotein (HDL) cholesterol concentration in the blood[3]. It is the key risk factor for most of the life threatening non communicable diseases like cardio vascular disease, diabetes, hypertension etc. Since synthetic drugs have been shown to have side effect, clinical importance of metallic and herbal drugs in the treatment of Dyslipidemia has received considerable attention in recent years. The metallic drug Vang Bhasma[4] and poly herbal formulation Navaka Guggulu[5] are described as Medohara i.e. Anti-dyslipidemic drugs in Ayurvedic classics. Hence the proposed study was undertaken to evaluate and establish the Medohara effect of Vang Bhasma alone and Vang Bhasma with Navaka Guggulu.

Aims and objectives

1. To evaluate the therapeutic efficacy of Vang Bhasma in the relief in symptoms of Medo Roga (Dyslipidemia).
2. To evaluate the therapeutic efficacy of Vang Bhasma with Navaka Guggulu in the relief in symptoms of Medo Roga (Dyslipidemia).
3. To compare the effect of Vang Bhasma alone and Vang Bhasma with Navaka Guggulu in the relief in symptoms of Medo Roga (Dyslipidemia).

MATERIALS AND METHODS

It was an open clinical trial with randomized sampling. The trial drugs Vang Bhasma and Navaka Guggulu were selected on the basis of classical references as well as modern knowledge of drugs. Vang Bhasma is calcinated form of Vang (Tin) while Navaka Guggulu is a poly-herbal formulation prepared from nine herbs along with Shuddha Guggulu[5]. [Table 1]

Ethical clearance- The proposed clinical study was presented in form of synopsis in front of Institutional Ethical Committee (IEC) of Rajiv Gandhi Govt. P.G. Ayurvedic College, Paprola, Distt. Kangra, Himachal Pradesh. The clinical trial was started after getting the approval from the Secretary of IEC vide letter no. IEC/2015/1047 dated 16-06-2015.

Method of collection of data- A special proforma was prepared incorporating demographic data of patients, detailed clinical history and all the clinical manifestation and assessment criteria of Medo Roga including laboratory investigations.

Selection of patients- 20 patients were selected for this study from O.P.D. of Department of Ras Shastra and Bhaishajya Kalpana, Rajiv Gandhi Govt. P.G. Ayurvedic College and Hospital, Paprola, Distt. Kangra, H.P. irrespective of their sex, religion and socio economic status. A written and informed consent of patients was taken before trial.

Inclusion Criteria

- Patients willing for clinical trial and ready to give written consent.
- Patients in the age group of 25 – 60 years of either sex.
- Patients possessing signs and symptoms of Medo Roga.
- Patients having Body weight more than the standard weight for their height.
- Patients with Body mass index >25.

Exclusion Criteria

- Patients not willing for the clinical trial.
- Patients not fulfilling the inclusion criteria.
- Patients below the age of 25 years and above the age of 60 years.
- Patients suffering from AIDS, Cancer, TB, Diabetes mellitus or any other severe systemic disorders.

Laboratory investigations- Serum cholesterol, HDL, LDL, VLDL, Serum Triglycerides.

Intervention- A total number of 20 patients willing for the trial and fulfilling the criteria for selection were selected for this study. They were randomly divided into two groups-

Group-I: 10 patients were registered in Group- I, in which 9 patients completed the trial and 1 patient left the treatment. These patients were treated with Cap. Vang Bhasma in the dose of 125 mg twice a day with lukewarm water. The duration of trial was 45 days.

Group-II: 10 patients were registered in Group- II, in which 9 patients completed the trial and 1 patient left the treatment. These patients were treated with Cap. Vang Bhasma in the dose of 125 mg twice a day and Cap. Navaka Guggulu in the dose of 500 mg twice a day with lukewarm water. The duration of trial was 45 days.

Criteria for assessment- To observe the effect of therapy, the patients were thoroughly assessed for improvement in subjective and objective criteria before and after the therapy on the basis of grading and scoring system. These criteria were-

Subjective criteria- Kshudra swasa (dyspnoea), Trishna (thirst), Nidra (sleep), Anga sada (malaise), Kshudha (hunger), Sweda (sweating), Daurgandhya (foul smelling of body) and Meda on udara (fat deposition on stomach)[6].

Objective criteria- Body weight more than the standard weight for their height and Body mass index>25[7]. [Table 2]

Statistical analysis- The scores of criteria of assessment were analyzed statistically in the form of Mean, Standard Deviation (± SD) and Standard Error (± SE). Student's Paired 't' test was applied to observe the significance of results. The results obtained were interpreted as Table 3.

OBSERVATIONS

Among 20 patients registered for the clinical study, 60% patients were in the age group of 25-40 years, 65% patients were female and all the patients were Hindu. 80% patients in this study were married. Maximum patients i.e. 55% reside in rural area. On considering education, 45% patients were graduated or higher educated. In this study, 35% patients were housewives followed by 30% patients were in Govt. job. Most of the patients i.e. 65% belonged to rich category of society, 50% patients were doing office work, 80% patients were having increased appetite, 60% patients were addicted to tea, 65% patients were having regular bowel habit and 65% patients had normal micturation pattern. In this study, 65% patients were of Vata Kaphaja Prakriti followed by 30 % patients of Pitta Kaphaja Prakriti.

Among various signs and symptoms; Kshudra Swasa, Nidra, Anga Sada, Kshudha, Sweda and Meda on Udara was observed in all the twenty (100%) patients, while Trishna was observed in ninteen (95%) patients and Daurgandhya was observed in fifteen (75%) patients. Body weight of all the patients was more than ideal weight for their height. BMI of 75% patients was in Grade-1, while 15% patients were in Grade- 0 and 10% patients in Grade- 2.

RESULTS

Group- I: The present study reveals that there was 69.7% improvement in Kshudra swasa, 73.07% improvement in Nidra, 57.57% improvement in Kshudha, 63.58% improvement in Sweda and 63.62% improvement in Meda on udara. These results were highly significant with $p<0.001$. On the other hand, there was 58.63% improvement in Trishna, 53.34% improvement in Anga sada and 46.14% improvement in Daurgandhya. These results were significant with $p<0.01$. There was 1.74% reduction in body weight and 2.14% reduction in BMI. Both the results were highly significant with $p<0.001$. The percentage relief in Serum Cholesterol, HDL, LDL, VLDL and Serum Triglyceride was 22.21%, 13.93%, 9.81%, 6.93% and 25.65% respectively. These results were insignificant with $p>0.05$. [Table 4]

Group- II: In Group- II, there was 70.96% improvement in Kshudra swasa, 59.25% improvement in Trishna, 69.99% improvement in Nidra, 54.54% improvement in Anga sada, 60.72% improvement in Kshudha and 66.64% improvement in Meda on udara. These results were highly significant with $p<0.001$. On the other hand, there was 56.01% improvement in Sweda and 53.85% improvement in Daurgandhya. These results were significant with $p<0.01$. There was 2.17% reduction in body weight and 3.17% reduction in BMI. Both the results were highly significant with $p<0.001$. The percentage relief in Serum Cholesterol, HDL, LDL, VLDL and Serum Triglyceride was 41.24%, 18.25%, 9.19%, 16.83% and 30.01% respectively. These results were insignificant with $p>0.05$. [Table 4]

Table 1: Ingredients of Navaka Guggulu

Name	Botanical Name	Part used	Ratio
Shunthi	*Zingiber officinale* Roxb.	Rh.	1 Part
Maricha	*Piper nigrum* Linn.	Fr.	1 Part
Pippali	*Piper longum* Linn.	Fr.	1 Part
Chitraka	*Plumbago zeylanica* Linn.	Rt.	1 Part
Haritaki	*Terminalia chebula* Retz.	Fr. P.	1 Part
Amalaki	*Emblica officinals* Gaertn.	Fr. P.	1 Part
Bibhitaka	*Terminalia belerica* Roxb.	Fr. P.	1 Part
Mustaka	*Cyperus rotundus* Linn.	Rh.	1 Part
Vidanga	*Emblica ribes* Burm.	Sd.	1 Part
Shuddh Guggulu	*Commiphora mukul* Hook ex Stocks.	Exd.	9 Part

Table 2: Grading of Body Mass Index (BMI)

Category	Grade	BMI
Under weight	-	<18.5
Normal	-	18.5 - 24.9
Over weight	Grade – 0	25 - 29.9
Obese	Grade – 1	30 - 34.9
	Grade – 2	35 - 39.9
	Grade – 3	>40

Table 3: Interpretation of statistical values

'p' Value	Result
p>0.05	Insignificant
p<0.05	Significant
p<0.01	Significant
p<0.001	Highly significant

Table 4: Effect of therapy on both groups

Parameters	Group- I				Group- II			
	Mean Score		% relief	p value	Mean Score		% relief	p value
	BT	AT			BT	AT		
Subjective Parameters								
Kshudra Swasa	3.667	1.111	**69.7%**	<0.001	3.444	1.000	**70.96%**	<0.001
Trishna	3.222	1.333	**58.63%**	<0.01	3.375	1.375	**59.25%**	<0.001
Nidra	2.889	0.778	**73.07%**	<0.001	3.333	1.000	**69.99%**	<0.001
Anga Sada	3.333	1.556	**53.34%**	<0.01	3.667	1.667	**54.54%**	<0.001
Kshudha	3.667	1.556	**57.57%**	<0.001	3.111	1.222	**60.72%**	<0.001
Sweda	3.111	1.444	**63.58%**	<0.001	2.778	1.222	**56.01%**	<0.01
Daurgandhya	1.857	1.000	**46.14%**	<0.01	2.167	1.000	**53.85%**	<0.01
Meda on Udara	3.667	1.333	**63.62%**	<0.001	3.667	1.222	**66.64%**	<0.001
Objective Parameters								
Body weight	76.667	75.333	**1.74%**	<0.001	76.778	75.111	**2.17%**	<0.001
BMI	31.286	30.614	**2.14%**	<0.001	31.211	30.219	**3.17%**	<0.001
Laboratory Investigations								
Serum Cholesterol	205.8	160.1	**22.21%**	>0.05	294.6	173.1	**41.24%**	>0.05
HDL	48.8	55.6	**13.93%**	>0.05	50.4	59.6	**18.25%**	>0.05
LDL	119.3	107.6	**9.81%**	>0.05	103.4	93.9	**9.19%**	>0.05
VLDL	33.2	30.9	**6.93%**	>0.05	40.4	33.6	**16.83%**	>0.05
Serum Triglyceride	188.3	140.0	**25.65%**	>0.05	223.9	156.7	**30.01%**	>0.05

BT: Before Treatment, AT: After Treatment

Table 5: Inter group comparison of therapy

Parameters	% Relief		% Difference	p value
	Group- I	Group- II		
Subjective Parameters				
Kshudra Swasa	69.7%	70.96%	**1.26%**	>0.05
Trishna	58.63%	59.25%	**0.62%**	>0.05
Nidra	73.07%	69.99%	**3.08%**	>0.05
Anga Sada	53.34%	54.54%	**1.2%**	>0.05
Kshudha	57.57%	60.72%	**3.15%**	>0.05
Sweda	63.58%	56.01%	**2.43%**	>0.05
Daurgandhya	46.14%	53.85%	**7.71%**	>0.05
Meda on Udara	63.62%	66.64%	**3.02%**	>0.05
Objective Parameters				
Body weight	1.74%	2.17%	**0.43%**	>0.05
BMI	2.14%	3.17%	**1.03%**	>0.05
Laboratory Investigations				
Serum Cholesterol	22.21%	41.24%	**19.03%**	>0.05
HDL	13.93%	18.25%	**4.32%**	>0.05
LDL	9.81%	9.19%	**.62%**	>0.05
VLDL	6.93%	16.83%	**9.9%**	>0.05
Serum Triglyceride	25.65%	30.01%	**4.36%**	>0.05

Table 6: Overall effect of therapy

Effect	Group- I		Group- II	
	No. of patients	Percentage	No. of patients	Percentage
No Improvement	0	0 %	0	0 %
Mild Improvement	0	0 %	0	0 %
Moderate Improvement	4	44.4 %	3	33.3 %
Highly Improvement	5	55.6 %	6	66.7 %
Complete Remission	0	0 %	0	0 %

Table 7: Rasa panchaka of ingredients of Navaka Guggulu

Dravya	Rasa	Guna	Vipaka	Virya
Shunti	Katu	Laghu, Snigdha	Madhura	Ushna
Maricha	Katu	Laghu, Tikshna	Katu	Ushna
Pippali	Katu	Laghu, Snigdha, Tikshna	Madhura	Anushna Sheet
Chitraka	Katu	Laghu, Ruksa, Tiksna, Ushna	Katu	Ushna
Haritaki	Pancharasa	Laghu, Ruksa	Madhura	Ushna
Amalaki	Pancharasa	Guru, Ruksh, Sheet	Madhura	Sheeta
Bibhitaka	Kashaya	Laghu, Ruksha,	Madhura	Ushna
Mustaka	Katu, Tikta	Laghu, Ruksha,	Katu	Sheeta
Vidanga	Katu	Laghu, Ruksha, Tikshna	Katu	Ushna
Guggulu	Katu, Tikta	Laghu, Ruksha, Tikshna, Vishada, Sukshma	Katu	Ushna

Inter-group comparison- It shows that there was no statistically significant difference in the effect of therapy on all the cardinal symptoms with p>0.05. Although percentage relief in the cardinal symptoms was more in Group- II (61.50%) than that in Group- I (60.71%). The percentage relief in Body weight and BMI was also more in Group- II than that in Group- I. [Table 5]

Overall effect of the therapy- Among 9 patients of Group- I, 4 patients (44.4%) were moderately improved while 5 patients (55.6%) were highly improved. In Group- II, 3 patients (33.3%) were moderately improved while 6 patients (66.7%) were highly improved. [Table 6]

DISCUSSION

This clinical study was conducted to evaluate the efficacy of Vang Bhasma alone and Vang Bhasma with Navaka Guggulu in the relief in symptoms of Medo Roga and also to compare the effect of both drugs. The outcome of the study showed ample evidence in regard to action of these drugs. These drugs were prepared in Charak Govt. Ayurvedic Pharmacy, Paprola, Distt. Kangra, Himachal Pradesh.

Ayurvedic pharmacology depends on five principles of Rasa, Guna, Vipaka, Virya and Prabhava[8]. Acharya Charaka has mentioned that any Dravya can have similar Rasa, Vipaka and Virya but a different mode of action which can be explained on the basis of Prabhava[9].

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 excessive increase and accumulation of Medo dhatu. It also causes Medovaha srotosanga, which causes Margavrodha of vayu. Both these factors lead to clinical presentation of Medo Roga[10].

In the Samprapti of Medo Roga, Kapha is main Dosha and Meda is main Dushya, while Agnimandya takes place at Medo dhatvagni level[11]. 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 Vang Bhasma and Navaka Guggulu fulfilled all these requirements. They helped in Samprapti vighatan a 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 pacify the symptoms of Medo Roga.

Probable mode of action of Vang Bhasma- The drug Vang Bhasma by its property of Tikta, Katu Rasa, Laghu, Ruksha Guna, Ushna Virya and Katu Vipaka[12] will have corrected Kapha dushti, which is main culprit in Samprapti of Medo Roga. Along with this, it contains Katu Rasa, Laghu, Ruksha, Tikshna Guna, Katu Vipaka and Ushna Virya[12]. 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. Again, these properties act at the level of Dhatvagni facilitating metabolism of Fat. Once the metabolism control is achieved, the pathological changes and Lipid profile which occur mostly due to metabolic dysfunction gets rectified. The pharmacological action like Medohara and Lekhana[12] may be helpful in reducing Abaddha meda and also facilitating normalization of Medo dhatu vriddhi.

Probable mode of action of Navaka Guggulu- On the basis of Rasa panchaka[13] [Table 7], the probable mode of action of Navaka Guggulu in Medo Roga can be explained.

In Medo Roga, Kapha dushti is the main cause of the disease[14]. Because of Laghu, Tikshna, Ruksha Gunas, Katu Rasa, Katu Vipaka and Ushna Virya of ingredients of Navaka Guggulu, it subsides the aggravated Kapha and relieves Medo Roga.

From the Samprapti of Medo Roga, it is clear that the main Dushya involved is Medo dhatu[14]. The combination shows dominance of Katu Rasa, Laghu, Ruksha, Tikshna Guna, Katu Vipaka and Ushna Virya. These all properties pacify Dushti of Medo dhatu. Thus, this combination acts on Medo Roga.

By the virtue of its Katu, Tikta Rasa, Laghu, Tikshna, Ruksha Guna and Ushna Virya, it stimulates Jatharagni which turn by turn stimulates Medo dhatvagni. This corrects the basic pathology of Medo Roga.

An Ama means unripen and undigested Anna rasa[15]. By the virtue of its Katu, Tikta Rasa, Laghu, Tikshna, Ruksha Guna and Ushna Virya, Navaka Guggulu will stop the further Ama production and help into break the basic pathology of Medo Roga.

The disease exhibits Sanga type of Sroto Dushti. The combination by the virtue of Laghu Guna, Tikta Rasa and Ushna Virya relieves Sanga type of Dusti and breaks the Samprapti of Medo Roga.

CONCLUSION

In the present study, both drugs were effective in relieving signs and symptoms of Medo Roga and also possess significant effect in normalizing the lipid profile. Although there was statistically significant relief in both the groups, yet Vang Bhasma with Navaka Guggulu in Group- II showed better relief in symptoms without any statistically significant difference. No adverse effect was noted during the treatment and follow up period in both the groups. However, this is only a preliminary study conducted as a part of educational research program with small number of patients for a short duration of time, further multi-centric, clinical and experimental studies are required with larger sample size to establish Medohara (anti-dyslipidemic) effect of these drugs.

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