Original Article

Management of *Sthula Madhumeha* with *Ghanasatva* of *Kadar, Khadir & Guggulu -* A Clinical Study

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Abstract:

Alteration in life style in the present days, results in manifestation of several life threatening disorders like I.H.D., diabetes mellitus, obesity etc. In future Ayurvedic science also commented regarding the importance of *Ahara* and *Vihara* for maintaining normal health status. *Sthula Madhumeha* is one of such diseases with very rapid incidence and is a type of *Santarpanajanya vyadhi. Shaman & Shodhana* modalities of treatment has been explained as its management tool. After reviewing previous works done on *Madhumeha,* it was found that *Ghanasatva* of *Kadar, Khadir & Guggulu* have not been studied till now. So the *Apatarpaka* effect of the said drug was evaluated & the results observed are mentioned in full paper.

Keywords: *Sthula, Madhumeha, Shaman, Shodhana, Apatarpana*

Introduction

Ayurveda has stressed upon the concept of total health for which multi dimensional unique concepts have been explained to achieve its goal of maintaining total health & curing the disease. In this context certain rules for proper life style are also explained. Life style disorders like *Sthulata & Madhumeha* are increasing now days. The incidence of *Sthula Madhumeha* is rising very rapidly which is very hazardous as it is one of the *Kulaj Vikar.* Keeping this in mind the study was planned. *Vagbhat* has advised the *Kvatha* of *Kadar, Khadir & Guggulu* as *Apatarpaka* for managing the patients of *Sthula Madhumeha* (A.S.C. 14/33). But instead of *Kwatha, Ghanasatva* of the said drugs was given to one group of 20 patients of *Sthula Madhumeha* because it is easy to take.

Sthula Madhumeha in *Ayurvedic* perspective is just like type II diabetes. Symptoms mentioned in *Ayurveda* are similar to type II diabetes. According to Hunter John, diabetic having BMI more than 23 should be treated as type II diabetes i.e, *Sthula Pramehi*.

Park predicted that number of patients of type II diabetes is going to be doubled in 2025. Ramchandran A, et al mentioned that prevalence rate in different parts of urban India is 12 to 18. He pinpointed, that the prevalence at national level is 12.1.This increase in prevalence is attributed to different causes such as increased monthly family income, age, gender family history, reduced physical activity.

There are so many researches done to control diabetes mellitus till now, but still this disease is not completely curable. There are many complications of diabetes mellitus such as diabetic retinopathy, diabetic neuropathy, diabetic ketoacidosis, hyperglycemic hyperosmolar state,

coronary heart disease, cerebrovascular disease & others, so this disease is called as Silent Killer. Therefore it is necessary to control blood sugar level to avoid complications.

One can only control the blood sugar level along with medicine. For control of Diabetes mellitus diet regimen, exercise, proper lifestyle is also important. At present many drugs are available to control the blood sugar level in type II diabetes but still complications are observed in many patients. It was assumed that Ayurvedic contention of treatment of *Sthula Madhumeha* will be helpful. According to *Sushruta Apatarpana* is to be administered to *Apathyanimittaj* type of *Prameha* (S.C.1/4). According to Dalhana, *Apatarpana* is *Langhana*. Further Dalhana added that *Apatarpana* includes administration of *Vyayama, Shodhana* or the drugs having *Katu and Tikta Rasa* (Dal.Com.S.C.11/4),by virtue of these properties of these *Apatarpaka* drugs might be acting on *Abaddha Meda* and more *Kapha* having *Drava* property so that *Meda and Kapha* will be reduced. This concept will be helpful to decrease the weight or BMI of particular *Sthula Madhumehi* i.e. type II diabetics. This concept of management might be helpful to control blood sugar level and may avoid consequences like diabetic complications. Therefore the drugs having these properties were thought of. As mentioned in *Astanga Sangraha* herbal formulation of *Apatarpaka* drugs such as *Kadar, Khadir* and *Guggulu* were selected to control blood sugar level and to bring down weight.

Materials & Methods

40 patients of *Sthula Madhumeha* were randomly selected from OPD & IPD of Kayachikitsa dept., Govt. Ayurved Hospital,Nagpur irrespective of sex, socio economical status & religion.

Study Design

The study was carried out in two groups (trial & control) of patients of *Sthula Madhumeha*. Both groups comprised of 20 patients each.

Selection of Drug:

The patients of trial group were given the *Ghanasatva of Kadar* (Acasia Suma), *Khadir* (Acasia Catechu) & *Guggulu* (Commiphora Mukul) in the dose of 1 gm Bid with lukewarm water before meals for 6 weeks. The patients of control group were given Tab. Glibenclamide 5 mg OD with water before meals for 6 weeks. All the patients were explained about particular *Ahar & Vihar* with respect to *Sthula Madhumeha*. Light diet was prescribed in divided timings and sweets were restricted from diet.

Criteria of Selection: Selection of the patients was made on the basis of following criteria:

1.Clinical signs & symptoms of *Sthula Madhumeha*

2.BMI more than 25 were selected

3.Fasting blood sugar less than 220 mg/dl and Post prandial blood sugar less than 400 mg/dl

4.Serum cholesterol less than300 mg/dl

5.Serum triglycerides less than 250 mg/dl

Criteria of Rejection: Rejection of the patients was made on the basis of following criteria:

1.BMI less than 25 were rejected

2.Fasting blood sugar more than 220 mg/dl and Post prandial blood sugar more than 400 mg/dl

3.Serum cholesterol more than300 mg/dl

4.Serum triglycerides more than 250 mg/dl

5.Patients having complications like diabetic neuropathy, nephropathy, retinopathy, vasculopathy, Myocardial infarction were rejected.

Criteria of Assessment: The patients were assessed on the basis of following criteria:

1.Effect of *Apatarpak* drug on symptoms of *Sthula Madhumeha.*

2. To evaluate the effect of drug on the quantity of Urine & sugar in urine.

3.To evaluate the effect of drug on weight & BMI.

4.To study the effect of drug on fasting and post meal blood sugar level.

5.To study the effect of drug on lipid profiles.

A criterion's for General Symptom Score:

Scoring was done as described by Kagde S. T. (2000) as follows:

A. 2 marks for each symptom before treatment for moderate condition and 3 for severe condition.

B. 1 mark was allotted after remarkable reduction of symptoms after the treatment.

C. Complete reduction in symptom was considered as zero mark.

D. No change in symptom after treatment was taken as 2 marks.

Observation

The study was carried out in 40 Patients of *Sthula Madhumeha*. Two groups comprising 20 patients each viz. treated group (T.G.) and control group (C.G.) were made. Patients of treated group were given *Ghanasatva* of *Kadar, Khadir* and *Guggulu* while that of control group were given Tab. Glibenclamide 5 mg OD. Patients who are having B.M.I. more than 25 were considered as overweight i.e. *Sthula* with fasting blood sugar level less than 220 mg/dl and post meal blood sugar level less than 400 mg/dl were selected for the said study.

All the clinical parameters, physical characters, hematological and biological parameters were noted one day before starting the treatment and were considered as before treatment (B.T.) values. The course of the treatment was of 6 weeks in both groups. One day after the completion of the course all the parameters were again recorded as after treatment (A.T.) values. However three patients each of treated and control group were not ready for lipid profiles due to some unknown reasons best known to themselves. Following observations were made after the completion of the study:

Kapha Vriddhi Lakshanas were relieved on average by 57% in treated group as compared to 14.29% in control group. In the same manner *Rasa Dhatu Dushti Lakshanas* were reduced on average by 37.98% in treated Group as compared to 17.59% in control group.

More than 50% of the relief in the patients of treated group in some symptoms like *Mukh Madhurya, Supti, Daha, Trishnadhikya, Alasya, Nidradhikya, Tandra, Mutradhikya, Avil Mutrata, Kshudhadhikya, Anutsaha, Daurbalyata* and *Svedadhikya* was observed which was more in treated group as compared to control group except *Mukh Madhurya*.

Weight in Kg in the patients of treated group was significantly reduced by 1.9 ± 0.72, t= 11.7719 and P‹0.001. In the same manner weight was also reduced in control group as presented in Table-4.

As we go through Table-4 it was observed that B.M.I. was also significantly reduced in both the groups (Table-4).

Ayurvedic concept of "*Madhuryat cha Tanorata*" was tested with respect to Fasting and post meal blood sugar level in the patients. F.B.S. in treated group was reduced very highly significantly as presented in Table-5; t was 8.630, P‹0.001 while in case of control group it reduced insignificantly. As presented in Table-5, post meal blood sugar levels of patients in both groups were reduced very highly significantly.

It is highlighted that only 34 patients were evaluated before and after the treatment with respect to lipid profiles. As presented in Table-6, only Serum triglycerides levels were significantly brought down in both the groups. Data highlighted in Table-6 proved it.

To decide better drug to reduce triglyceride levels unpaired T-test was carried out. Unpaired T-test was 2.7518, P‹0.01. This statistical analysis proves that one of the groups was better between them. The drug in control group was responsible for that (Table-7).

Quantity and specific gravity of urine was decreased by the respective therapies in both the groups. However statistical results showed that it was insignificant.(Table-08)

Table 9 showing Total Effect of the Therapy

indicated that 65% of the patients in treated group and 50% of the patients in control group were markedly improved. While 35% of treated group patients and 45% of control group patients were improved. One patient of control group remains unchanged after the completion of the therapy. It is very clear that treated group was better than that of control group.

Scientific Analysis of Results

In this study 40 patients of *Sthula Madhumeha* i.e. patients suffering from diabetes mellitus who had B.M.I. more than 25 were studied. Patients of this study were selected randomly irrespective of age, sex, religion and socio-economical status. The patients were selected as per the criteria of selection. Six of them did not turn up for the follow up of lipid profiles for unknown reasons.

Table-1 shows that most of the symptoms were relieved by more than 50% in treated group may be due to the properties of trial drug. In control group also there was fair percentage of relief. However it was more in treated group.

The effect of drug was observed on a unique contention of Ayurveda i.e. *Dosha Vriddhi Lakshana* and *Dhatu Dushti Laskshana*. Table-2 and 3 highlighted effect of drug on *Dosha Vriddhi Lakshana* score and *Dhatu Dushti Lakshana* respectively. More reduction in treated group was observed in *Vata- Kapha* and *Pitta Vriddhi Lakshana* score. These tables suggest that the drug in treated group had more percentage of relief than control group.

Weight and B.M.I. were evaluated in all the patients. Table-4 suggested that the drug in treated group and control group highly significantly reduced weight and B.M.I. So unpaired t-test was carried out for the comparison between two independent treated and control group.

Effect on fasting and post meal blood sugar level was also evaluated in all the patients. Table-5 shows that very highly significant reduction (diff. of mean= 31.915 mg/dl) in F.B.S. of patients in treated

group, while in case of control group reduction F.B.S. was insignificant. In case of P.M.B.S. in treated group reduced by 48.325 mg/dl t= 4.6076, P < 0.001. In the same manner P.M.B.S. in control group was also reduced very highly significantly. Therefore further comparison between the levels of P.M.B.S. in both groups was carried out by unpaired t test.

The effect of drugs in both groups on total cholesterol, HDL, LDL was noted. Reduction in total cholesterol in both groups was insignificant. There was a marginal insignificant increase in HDL while LDL in both groups increased by very marginal levels which did not show any significant role. Effect on triglycerides in both groups noted was favorable. Reduction in treated group was significant while in control group it was more significant (Table-6).

As significant reduction in triglycerides prompted to evaluate the better drug for that unpaired t test for unmatched data was carried out (Table-7).

Comparison between the two groups: It was observed that weight, B.M.I., P.M.B.S. and triglycerides reduced significantly at different levels of significance in both groups. Therefore further comparison of two independent groups was carried out by unpaired t test, which is highlighted in Table-7.

Difference of mean of weight in T.G. was 1.9 ± 0.72 which was more by 0.52 kg weight than the difference of mean in C.G. This difference was tested statistically by unpaired t test; t was 2.3985, P < 0.05. The result was significant. More difference of mean of weight in T.G. Was clearly suggestive that weight in T.G. reduced significantly.

Similarly B.M.I. was also reduced very highly significantly as presented in Table-7. Mean difference of B.M.I. was observed more in T.G. in comparison to C.G. and was found to be highly significant.

As both group exhibited significant difference of mean in P.M.B.S. Therefore difference of both groups were statistically tested. Their difference was insignificant as highlighted in Table-7.

Difference exhibited in patients of T.G. was compared with that of in C.G. with respect to triglycerides values. More diff. of means shown in C.G. by 24.04 mg/dl was found to be highly significant i.e. the drug in control reduced triglycerides in C.G. (Table-7).

Probable mode of Action of Trial drug

Kadar, Khadir and *Guggulu* in equal proportion were taken and its compound *Ghanavati* was prepared. This *Ghanavati* have *Tikta-Katu Rasa, Shita Virya, Laghu-Ruksha Guna* and *Katu Vipaka*. This drug has the action on *Vata, Pitta* and *Kapha Dosha*. Alleviation of *Kapha* may be more potently done as compared to *Pitta* and *Vata*. *Dushti* of *Meda* has been exclusively mentioned as *Bahu* and *Abadhha Meda*. This drug by virtue of its maximum *Rasa* (50% of *Tikta Rasa*) might be enhancing *Pachan* of *Meda* ultimately by increasing *Dhatvagni* of *Meda*; reduction in weight and B.M.I. was observed. *Guggulu* in this compound might be spreading all over the mucous membrane of the intestine where the absorption of glucose is mentioned. Layer of this drug on mucous membrane may restrict the absorption of *Madhur Rasa*. Thus over all blood sugar level might have been reduced significantly in treated group. The drug was given for the duration of six weeks in this study; however long term indulgence of this compound may show more reduction in B.S.L., weight and B.M.I.

Discussion and Conclusion

It is very evident from the observations and results of the study that *Apatarpaka* drug definitely reduced *Meda Dhatu* which has important role in manifestation of *Madhumeha*. The significant reduction in weight, BMI, blood sugar level, specific gravity and quantity of urine and serum triglycerides established efficacy of the *Ghanasatva* of *Kadar, Khadir* and *Guggulu* on *Sthula Madhumeha*. If fore said herbal formulation is used for prolonged period*,* it might definitely affect *Sthula Madhumeha* and

consequently may help to restrict hazardous complications.

Although none of the patients was cured, maximum patients of treated group were markedly improved and remaining were improved as compared to control group which proves the Ayurvedic contention of *Apatarpana Chikitsa* on *Sthula Madhumeha*.

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Table–01: Showing Effect of *Apatarpaka* Drug on Symptom Score in 40 Patients of *Sthula Madhumeha*

Sr. No.	Symptoms	Groups	Symptom Score			%age relief
			BT	AT	Diff	
1	*Mukha- Madhurya*	Treated	44	15	29	65.90
		Control	38	12	26	68.42
2	*Supti*	Treated	20	07	13	65
		Control	10	05	05	50
3	*Daha*	Treated	38	13	25	65.79
		Control	29	12	17	58.62
4	*Trishnadhikya*	Treated	46	16	30	65.22
		Control	38	15	23	60.53
5	*Alasya*	Treated	37	18	19	51.35
		Control	40	21	19	47.5
6	*Maladhikya*	Treated	13	08	05	38.46
		Control	06	05	01	16.67
7	*Nidradhikya*	Treated	28	12	16	57.14
		Control	25	13	12	48
8	*Tandra*	Treated	24	11	13	54.17
		Control	14	09	05	35.71
9	*Mutradhikya*	Treated	51	20	31	60.75
		Control	48	25	23	47.92
10	*Aavil Mutrata*	Treated	29	11	18	62.07
		Control	30	13	17	56.67
11	*Kshudhadhikya*	Treated	28	10	18	64.29
		Control	18	10	08	44.44
12	*Medadhikya*	Treated	47	25	22	46.81
		Control	42	24	18	42.86
13	*Anutsaha*	Treated	31	15	16	51.61
		Control	36	20	16	44.44
14	*Sakashta Maithun*	Treated	09	07	02	22.22
		Control	06	06	00	00.00
15	*Durbalata*	Treated	47	17	30	63.83
		Control	40	19	21	52.5
16	*Durgandhi Sharir*	Treated	18	12	06	33.33
		Control	10	09	01	10
17	*Svedadhikya*	Treated	45	16	29	64.44
		Control	34	17	17	50.00

Table -2: Showing Effect of Therapy on Dosha Vriddhi Lakshana Score in 40 Patients of Sthula Madhumeha

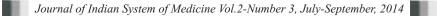| SN	Dosha Vridhhi Lakshana	Symptom score						Percentage of Relief	
		Treated Group			Control Group				
		B.T.	A.T.	Diff	B.T.	A.T.	Diff	T.G.	C.G.
1	Vata Vriddhi Lakshana								
A	Bhrama	12	04	08	14	10	04	66.67	28.57
2	Pitta Vriddhi Lakshana								
A	Shita Kamita	28	18	10	24	19	05	35.71	20.83
3	Kapha Vriddhi Lakshana								
A	Gauravam	14	10	04	14	12	02	57	14.29
B	Sada	14	10	04	12	10	02	28.57	16.66
C	Tandra	24	11	13	14	09	05	54.17	35.71
D	Shvasa	30	24	06	33	29	04	20	12.12
E	Atinidra	30	18	12	32	28	04	40	12.5
4	Total of Kapha Vriddhi Lakshana	112	73	39	105	88	17	34.82	16.19

Table -3: Showing Effect of Therapy on Dhatu Dushti Lakshana in 40 Patients of Sthula Madhumeha

S.N.	Dhatu Dushti Lakshana	Symptom score						Percentage of Relief	
		Treated Group			Control Group				
		B.T.	A.T.	Diff	B.T.	A.T.	Diff	T.G.	C.G.
A	Rasa Dhatu								
1.	Asya Vairasya	24	11	13	26	20	06	54.17	23.077
2	Gaurav	14	10	04	14	12	02	57	14.28
3	Tandra	24	11	13	14	09	05	54.17	35.17
4	Angamard	12	08	04	08	07	01	33.33	12.5
5	Srotorodha	20	14	06	20	18	02	30	10
6	Klaibya	09	07	02	06	06	0	22.22	0
7	Sada	14	10	04	12	10	02	28.57	16.67
8	Wrinkles on Skin	12	09	03	08	07	01	25	12.5
9	Total score	129	80	49	108	89	19	37.98	17.59
B 1	Meda Dhatu Udar Stana Chala Sphik	47	25	22	42	34	18	48	42
2	Nirutsaha	31	15	16	37	20	17	51.61	45.95
C1	Majja Dhatu Bhrama	12	04	08	14	10	04	66.67	28.57
D1	Shukra Dhatu Klaibya	09	07	02	06	06	00	22.22	0

Table 4: Showing Effect of Therapy on Weight & BMI of 40 Patients of *Sthula Madhumeha*

S.N.	Parameters	Groups	Mean ± SD		Diff. Of Mean ± SD	SEd	T	P
			BT	AT				
1	Weight in kg	Treated	70.15 ± 11.86	68.25 ± 11.94	1.9 ± 0.72	0.16140	11.7719	<0.001
		Control	65.25 ± 11.93	63.87 ± 11.97	1.38 ± 0.65	0.145	9.2	<0.001
2	BMI in kg/m^2	Treated	29.60 ± 3.91	28.62 ± 3.822	0.98 ± 0.620	0.13825	7.099	<0.001
		Control	27.87 ± 3.799	27.240 ± 3.623	0.630 ± 0.370	0.083	7.6265	<0.001

Table 5: Showing Effect Of Therapy On Blood Sugar Level of 40 Patients of Sthula Madhumeha

S.N.	Parameters	Groups	Mean ± SD		Diff. of Mean SD	SEd ±	T	P
			BT	AT				
1	Fasting Blood Sugar Level	Treated	145.0 ± 26.94	113.09 ± 19.995	31.92 ± 16.54	± 3.689	8.630	<0.001
		Control	161.99 ± 50.02	120.26 ± 34.997	41.73 ± 25.54	± 5.711	1.347	>0.1
2	Post Meal Blood Sugar Level	Treated	231.64 ± 67.25	183.32 ± 40.87	48.33 ± 46.91	± 10.488	4.608	<0.001
		Control	255.26 ± 77.79	192.05 ± 53.48	63.22 ± 50.55	± 11.304	5.592	<0.001

Table 6: Showing Effect of Therapy on Lipid Profiles by Paired "t" Test of 40 Patients of Sthula Madhumeha

S.N.	Lipid Profile	Groups	Mean ± SD		Diff. Of Mean ± SD	SEd	T	P
			BT	AT				
1	Total Cholesterol in mg/dl	T.G.	198.541 ± 35.835	194.329 ± 42.436	4.212 ± 31.8028	7.7133	0.5460	>0.1
		C.G.	227.493 ± 51.070	197.012 ± 36.693	30.481 ± 59.6149	14.9037	2.0456	>0.5
2	HDL in mg/dl	T.G.	44.511 ± 5.758	46.871 ± 5.647	2.36 ± 5.654	1.3713	1.7209	>0.1
		C.G.	47.929 ± 8.755	48.105 ± 4.349	0.176 ± 9.098	2.206	0.0797	>0.1
3	LDL in mg/dl	T.G.	123.267 ± 33.81	127.11 ± 39.92	3.843 ± 31.365	7.607	0.501	>0.1
		C.G.	136.6235 ± 32.1156	137.1176 ± 33.8960	0.494 ± 32.516	7.887	0.0626	>0.1
4	Triglycerides in mg/dl	T.G.	159.523 ± 52.466	142.648 ± 51.135	16.877 ± 31.664	7.680	2.198	<0.05
		C.G.	192.094 ± 79.5180	151.1764 ± 38.1605	40.9176 ± 14.7853	14.7853	2.7674	<0.02

Table -7: Showing Comparison Between The Two Groups w.r.t. Weight, B.M.I., P.M.B.S. in 40 patients and Triglycerides in 34 Patients of Sthula Madhumeha by Unpaired "t" Test

Parameters in diff units	Diff. of means in T.G.	Diff. of means in C.G.	Diff. Bet. Means of Treated & Control	SEd	T	P
Weight	1.9 ± 0.72	1.38 ± 0.65	0.52	0.2168	2.3985	<0.05
B.M.I.	0.98 ± 0.62	0.63 ± 0.37	0.66	0.1614	4.0892	<0.001
P.M.B.S.	48.325 ± 46.905	63.215 ± 50.552	14.89	15.419	0.9659	>0.1
Triglycerides	16.88 ± 31.664	40.92 ± 14.785	24.04	8.736	2.7518	<0.01

S.N.	Urine Examinations	Groups	Mean ± SD		Diff. Of Mean ± SD		SEd	T	P
			BT	AT					
1	Quantity in ltrs	T.G.	2.1845 ± 0.374	1.8725 ± 0.2643	0.312 ± 0.1485		0.0332	9.397	<0.001
		C.G.	2.156 ± 0.243	1.852 ± 0.237	0.304 ± 0.171		0.038	8.00	<0.001
2	Specific Gravity	T.G.	1.01615 ± 0.005562	1.0098 ± 0.006771	0.00635 ± 0.003248		0.0007264	8.7417	<0.001
		C.G.	1.01865 ± 0.005203	1.0139 ± 0.006820	0.0049 ± 0.003210		0.0007178	6.8264	<0.001

Table 8: Showing Effect Of Therapy On Quantity and Specific Gravity of Urine of 40 Patients of Sthula Madhumeha

S.N.	Total Effect of Therapy	Groups	Total no. of Patients	Percentage
1	Cured	Treated	00	00
		Control	00	00
2	Markedly Improved	Treated	13	65
		Control	10	50
3	Improved	Treated	07	35
		Control	09	45
4	Unchanged	Treated	00	00
		Control	01	05
5	LAMA	Treated	00	00
		Control	00	00

Table 9: Showing Total Effect of Therapy on 40 Patients of *Sthula Madhumeha*