Research Article

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EFFECT OF SUDDH GUGGULU AND SUDDH SHILAJATU IN THE MANAGEMENT OF STHOULYA WITH SPECIAL REFERENCE TO METABOLIC SYNDROME

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ABSTRACT

Metabolic Syndrome is a new clinical entity which refers to the disorder of energy utilization and storage. This is diagnosed by a co-occurrence of 3 out of 5 of the following medical conditions: - central obesity, increased Blood Pressure, Impaired glycaemic state, increased Triglycerides, and decreased HDL (High density cholesterol) levels. The components of the metabolic syndrome cluster together are strongly associated with negative health outcomes especially in terms of cardiovascular health. Metabolic Syndrome is most commonly caused by a combination of excessive food intake, lack of physical activity, and genetic susceptibility. Metabolic Syndrome can be compared with a condition called Sthaulya in Ayurveda. In present single group study, 30 patients were selected on the basis of inclusion and exclusion criteria. Shuddh Shilajatu and Suddh Guggulu administered together before meals twice a day with lukewarm water for 45 days. Therapy was found effective in patients suffering from Metabolic Syndrome. The result was significant for most of the parameters.

Keywords: Sthoulya, Metabolic Syndrome, glycemic state, cholesterol, BMI, Triglyceride, HDL.

INTRODUCTION

A syndrome consisting of a cluster of metabolic and cardiovascular risk factors was first described in 1988, when it was noted that insulin resistance was associated with the causation and clinical course of type 2 diabetes, coronary artery disease and hypertension[1,2]. This question has since been the focus of a large volume of research. Reaven (1988) originally termed the clustering of risk factors associated with insulin resistance as syndrome [3]. Other terms, such as the deadly quartet, cardiometabolic syndrome and obesity dyslipidemia syndrome are also used [4], but the most common term is the metabolic syndrome. The metabolic syndrome refers to the co-occurrence of the following cardiometabolic components: insulin resistance/impaired glucose tolerance, abdominal obesity, hypertension and dyslipidemia[5]. The components of the metabolic syndrome, cluster together is strongly associated with negative health outcomes[6]. Therefore, the metabolic syndrome as a concept is essential in that it puts a name, and thus a spotlight, on these inter-related risk factors.

On an average, 230 million people all over the world are suffering from metabolic diseases. Approximately 20-25 % of the world's adult populations have the cluster of risk factors i.e. metabolic syndrome[7].Some studies have shown the prevalence in the USA to be estimated 34% of the adult population[8]. Increased industrialization worldwide is associated with rising rates of obesity, which is anticipated to increase the prevalence of Metabolic Syndrome dramatically, especially as the population ages. Moreover, the rising prevalence and severity of obesity in children is initiating feature of Metabolic Syndrome in younger population [9]. Thus, the Metabolic Syndrome provides many challenges to government and healthcare providers.

Metabolic Syndrome can be understood in line with the description of Sthaulya or Medoroga in Ayurveda. Sthoulya has been considered as Ninditiya Vyadhi in Ayurvedic literature[10]. In this particular pathology, Vata which is obstructed by Medo dhatu enhances the activity of Agni in Koshtha, resulting in rapid digestion of food which in turn increases the craving of food[11]. As Meda obstruct the nourishment pathway, the other Dhatus do not get proper nourishment, resulting in the disproportionate increase of Meda. Charak Samhita has been described the symptoms of Sthoulya as Ayuhrasa (decreased life span), Javoprodha (decrease in enthusiasm and activity), Krichravyavayta (difficulty in sexual act), Daurbalya (decreased strength), Daurgandhya (bad odor), Swedabadha (excess perspiration), and Kshut Pipasadhikya (excessive hunger and thirst)[12]. This results mainly due to Rasa and Meda dusthi. Shudha Guggul [13, 14] and Shudha Shilajatu[15] single drug formulations were selected considering their special indication in obesity and Shilajatu's indication in Prameha also. Guggulu[16] and Shilajatu[17] are having Ushna and Anushanasheet Virya respectively, Tikta Rasa, Katu Vipaka, Tridoshashamaka- Rasayana Prabhava, which is required in the Sthoulya Samprapti Vighatan. This study was an attempt to evaluate the efficacy of Shuddha Shilajatu and Shudha Guggulu in the management of Sthoulya with special reference to Metabolic Syndrome.

Objectives

To evaluate the efficacy of Shudha Shilajatu and Shudha Guggulu in the management of Sthoulya with special reference to Metabolic Syndrome.

MATERIALS AND METHODS

Study Design

It was an open clinical trial. Patients were selected from Kayachikitsa OPD/IPD of the R.G.G.P.G., Ayurvedic College & Hospital Paprola, Kangra, Himachal Pradesh. Patients fulfilling the diagnostic and inclusion criteria were included in the present study. In total 30 patients were enrolled in the present study. Written and informed consent from the patients was also taken before inclusion in the trial.

Ethical clearance

The proposed clinical study was presented in the 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/2015/1012 dated 16-06-2015.

Diagnostic criteria

For diagnosis of Metabolic Syndrome, 2001 NCEP/ATP III criteria were adopted. Which is as follows:
Presence of ≥ 3 of the following 5 criteria

- Waist circumference > 90 cm in men; >80 cm in women
- SBP ≥ 130 mmHg and/or DBP ≥ 85 mmHg or taking medical treatment of the previously diagnosed case of HTN, Triglyceride (TG) ≥150 mg/dl
- HDL-c <40 mg/dl for men; <50mg/dl for women
- Fasting blood sugar >100 mg/dl, taking medical treatment of the previously diagnosed case of HTN.

Inclusion criteria

Patients of either sex aged between 20-60 years, having Metabolic Syndrome (according to NCEP/ATP III criteria), willing for trial and without any associated known co-morbidity were enrolled for trial.

Exclusion criteria

The Patients who have participated in any clinical trial during past 6 months or having stage II hypertension (≥ 160/100 mmHg) and/or diabetic patients having FBS > 200 mg/dl were excluded from this trial. Further, persons suffering from major medical diseases like cancer, concurrent infection like tuberculosis etc., genetic or endocrinal disorder, chronic disorder like paralysis, renal failure, hepatic failure & IHD, and pregnant/ lactating women were also not included in this study.

Laboratory investigations

Hb%, TLC, DLC, ESR, FBS, Serum cholesterol, HDL, LDL, VLDL, Serum Triglycerides, SGOT, SGPT, S. Urea, B. Creatinine, Urine- Routine & Microscopic.

Study Interventions

The patients were administered Shuddh Guggulu in a dose of 1gm (2 capsules of 500mg each) twice daily and Shuddh Shilajau in a dose of 500mg (2 capsules of 250mg each) twice daily for 45 days with follow up after every 15 days. Both the drugs were advised before meals and with lukewarm water. Both the Ayurvedic drugs were procured from Good Manufacturing Practice-certified Ayurvedic pharmaceutical industry. In total 30 patients were enrolled for the present study, out of them 3 discontinued the treatment during the course of trial. So, they were dropped out from the study and remaining 27 completed the full course of trial.

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. For subjective assessment grading and scoring system was adopted. These criteria were-

Subjective criteria

Chalasphikaudarastana (visible movement in hip-abdomen-breast), Alasya/Utsahahani (Laziness/Lack of enthusiasm) Kshudrashwasa/AyaseShvasa (dyspnoea on exertion), Daurbalyata-Alpa Vyayama (weakness), Nidra (sleep), Sweda (sweating), Daurgandhya (foul smelling of body), Snigdhangata (oily body luster), Trishna (thirst), Kshudha (hunger), Angagaurava (heaviness in the body), AlpaVyavaya (Less Libido), Anga sada (malaise) and Anga Shaithilya (flabbiness in the body).

Objective criteria

Body mass index, Body weight, Abdominal girth, Total body fat percentage, Visceral fat, Systolic blood pressure, Diastolic blood pressure, Total cholesterol, Triglyceride levels, HDL, LDL, VLDL, Hb gm%, FBS, and ESR.

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 1).

OBSERVATIONS

Among 30 patients registered for the clinical study, 50% patients were in the age group of 51-60 years, 57% patients were female, and all the patients were Hindu. 97% patients in this study were married. Maximum patients i.e. 47% resided in semi-urban area. On considering education, 47% patients were graduate or higher educated. In this study, 39% patients were housewives followed by 34% patients were businessmen on the ground of profession. Most of the patients i.e. 86% belonged to the middle class of society. 58% patients were enjoying sedentary lifestyle and doing no exercise in their daily routine (77%). Most of the patients were viewing TV for more than 2 hours (44%), walking daily for less than 1 Km (45%) and not practicing Yoga at all (60%). The maximum numbers of patients (62%) were having increased appetite (Tikshanagni) and were taking a mixed type of diet (73%). Majority of the patients i.e. 38 (41%) were taking breakfast occasionally and were taking major meal 3 times/day (54.34%) with three or more supplementary diets/day (55%). Mostly (59%) patients were taking junk food. Maximum patients were doing Adhyshana (55%), followed by Samashana (25%).

58% patients had Madhyama Koshtha followed by Krura Koshtha in 35%. Most patients were enjoying Madhur Rasa (64%). 37% patients were having disturbed sleeping pattern with daytime sleep was found in 86% patients. In this study, paramount (49 %) patients were of Kaphaja-pittaja Prakriti followed by 34 % patients of Kaphaja-vataja Prakriti,with Medo predominance in Sara (53%) , and of Pravara Samhanana .

Among various signs and symptoms; Alasya was found in 86.67% patients, followed by Nidradhikya and Atikshudha in 76.67%, Angaurava in 73.33% patients. Chalasphikaudarasatana, Daurbalya, Atipipasa were found in 70% patients while Swedadhikya and Gatrasada were observed in 63.33% patients. Daurgandhya was found in 60% patients and Snigdhangata was noticed in 53.33% of patients. Alpa Vyavaya was found in 40% of patients. ≥ 76Kg weight was found in the majority of the patients (53%), 80-89cm waist circumference was found in 40% patients, and B.M.I. ranging 30-34 was found in 60% patients. Maximum patients had very high total body fat (43% patients), very high visceral body fat levels (63% patients), and normal muscle percentage (53% patients).

RESULTS

The present study reveals that there was 2.38%, 3.48%, 24.63%, 13.91% and 2.42% reduction in body weight, abdominal girth, total body fat percentage, visceral fat, and B.M.I. respectively. The percentage reduction in systolic blood pressure, LDL, VLDL and Serum Triglyceride was 7.32%, 4.73%, 3.69 %, and 37.17% respectively. These results were highly significant with $p<0.001$. On the other hand, there was 5.28%, 6.51%, 20.57%, and 13.8% reduction in diastolic blood pressure, total cholesterol, ESR and FBS respectively. 12.24% improvement was calculated in HDL levels (Table 2-5). These results were statistically significant with $p <0.05$. 45%, 56.52%, 57.89%, 63%, 59%, and 63% improvement was found in Alasya, Ayaseshwasa, Daurbalya, Daurgandhya, and Atipipasa, atishudha respectively. These results were highly significant with $p<0.001$. However, Chalasphikudarastana, Nidraadhikya, Swedadhikya, Snigdhangata, Angagaurava, Alpavyavaya, Gatrasada and Angasaithilya were relieved by 30%, 39%, 53%, 30%, 46%, 4%, 30%, and 43% respectively. These results were statistically significant with $p<0.05$. (Table 4)

Table 1: 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 2: Effects of the therapy on Objectives parameters

Variable	N	Mean value		Percentage Change	±SD	±SE	't'	P
		BT	AT					
Weight (in kg)	27	77.22	75.37	2.38%	1.363	0.262	7.034	<0.001
Abdominal Girth (in cm)	27	95.78	92.44	3.48%	3.385	0.651	5.128	<0.001
Total body fat percentage	27	23.690	17.853	24.63%	3.66	0.668	8.734	<00.01
Visceral Fat	27	17.39	14.97	13.91%	1.408	0.257	9.413	<0.001
BMI (Kg/m^2)	27	29.720	29	2.42%	0.532	0.102	7.025	<0.001

BT: Before Treatment, AT: After Treatment

Table 3: Effect of therapy on blood pressure

Variable	Mean value		Percentage Change	±SD	±SE	't'	P
	BT	AT					
SBP (in mm Hg)	143.63	133.11	7.32%	7.13	1.37	7.65	<0.001
DBP (in mm Hg)	89.63	84.88	5.28%	7.52	1.44	3.27	0.003

BT: Before Treatment, AT: After Treatment

Table 4: Effects of the therapy on subjective parameters

Symptoms	N	Mean Score		Percentage Change	±SD	±SE	P
		BT	AT				
Chalaspikaudarastana	21	1.25	0.88	30%	0.50	0.13	0.0313
Alasya	26	1.85	0.85	45.23%	0.49	0.10	<0.001
Ayaseshwasa	18	1.44	0.63	56.52%	0.40	0.10	0.0002
Daurbalya	21	1.19	0.50	57.89%	0.48	0.12	0.001
Nidradhikya	23	1.13	0.69	38.89%	0.51	0.13	0.0156
Swedadhikya	19	1.19	0.56	52.63%	0.50	0.13	0.002
Daurgandhya	18	1.19	0.44	63.16%	0.45	0.11	0.0005
Snigdhangata	16	1.71	0.50	29.76%	0.76	0.58	<0.05
Atipipasa	21	1.38	0.56	59.09%	0.40	0.10	0.0002
Atikshudha	23	1.69	0.63	62.96%	0.44	0.11	<0.0001
Anganaurava	22	1.35	0.42	46.42%	0.49	0.10	<0.05
Alpavyavaya	12	0.73	0.60	4.44%	0.64	0.53	<0.05
Gatrasada	19	1.15	0.40	30%	0.43	0.23	<0.05
Angasaithilya	13	0.71	0.14	42.85%	0.53	0.32	<0.05

BT: Before Treatment, AT: After Treatment

Table 5: Effect of therapy on biochemical parameters

Variable (mg/dl)	Mean value		Percentage Change	±SD	±SE	't'	P
	BT	AT					
Total Cholesterol	191.115	133.154	29.82%	13.43	2.634	22.002	<0.001
TG	251.37	157.92	37.17%	66.58	12.814	7.292	<0.001
HDL	49	55	12.24%	9.450	1.819	3.29	0.003
LDL	102.85	88.9	12.63%	8.294	1.855	7.522	<0.001
VLDL	41.6	36.15	13.10%	3.069	0.686	7.942	<0.001

BT: Before Treatment, AT: After Treatment

Table 6: Effect of therapy on other biochemical parameters

Variable	Mean value		Percentage Change	SD	SE±	't'±	P
	BT	AT					
HB (g%)	11.159	12.35	10.67%	1.45	0.28	4.27	<0.001
TLC (mg/dl)	7285.71	6400	12.15%	2264.39	605.18	1.46	0.167
ESR (mmfall1st hr)	31.11	24.70	20.57%	10.98	2.11	3.03	0.005
FBS (mg/dl)	112.63	97.07	13.8%	25.50	4.90	3.16	0.004
Urea (mg/dl)	28.50	26.35	7.5%	8.50	2.72	0.94	0.363
Creatinine (mg/dl)	0.864	0.757	12.38%	0.23	0.61	1.74	0.105
Uric acid (mg/dl)	5.289	5	5.78%	1.58	0.52	0.54	0.598

BT: Before Treatment, AT: After Treatment

Table 7: Overall effects of the therapy

Results	No. of patients	Percentage
Excellent Response	04	14.81
Marked Response	13	48.14
Mild Response	09	33.33
No Response	01	3.33

Overall effect of the therapy

Among 27 patients, 4 (14.81%) showed excellent improvement while 13 patients (48.14%) markedly improved. Mild improvement was seen in 9 patients (33.33%), single patient did not show any response to the therapy. (Table 7)

DISCUSSION

The pathogenesis of Metabolic Syndrome is complex but central obesity seems to be a key factor to develop the syndrome. Hence, it seems very much appropriate to compare Metabolic Syndrome with Sthaulya. Sthaulya or Medo Roga results due to Shleshma vardhaka ahara and vihara, which causes the production of Ama rasa by suppressing Jatharagni. It further causes Medo dhatvagni mandya, resulting in the production of Ama meda. It leads to excessive increase and accumulation of Medo dhatu. It also causes Medovaha sroto-sanga, which causes Margavrodha of vayu. Both these factors lead to clinical presentation of Medo Roga[18]. In the Samprapti of Medo Roga, Kapha is main Dosha and Meda is main Dushya, while Agnimandya takes place at Medo dhatvagni level[19]. So, the drug which has Kapha and Medo nashaka property and has efficacy to correct the function of Medo dhatvagni, will give better result in the management of Medo Roga.

Fortunately, the drugs Shudhha Guggulu and ShudhaShilajatu fulfilled these requirements. They helped 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 pacify the symptoms of Medo Roga.

CONCLUSION

Sthaulya is a Dushya dominant Vyadhi, and it is comparable with Metabolic Syndrome. Obesity is the major driving force in the development of Metabolic Syndrome. In order to prevent Metabolic Syndrome, a multi-dimensional approach is essential, which should include behavior modification, dietary restriction and modification, increase in physical activities, incorporation of Yoga practices in daily routine. Treatment modality should be planned considering vitiated Meda, Kapha and Vata as they are the key factors in pathophysiological cascade. Suddh Guggul and Suddh Shilajatu provided promising results on symptomatology and objective parameters in management of Metabolic Syndrome. No adverse effect was noted during the trial.

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