



Research Article

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CLINICAL EVALUATION OF SHILAJATU (*ASPHALTUM PUNJABINUM*), KUTAKI (*PICRORHIZA KURROA*) AND KHADIR (*ACACIA CATECHU*) IN THE MANAGEMENT OF STHAULYA (OBESITY)

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ABSTRACT

Sthaulya (obesity) is the most common, frequent health related conditions that poses a considerable challenge to Ayurvedic physicians. It is one of the important risk factors and contributor for cardiac and cerebrum-vascular deaths globally since ancient time. Two thousand years ago, Acharya Charaka described Ashta Nindita Purusha and emphasized in detail about two pathological conditions viz Ati sthula and Atikarshya. Atisthula purusha is worst among them, due to its complicated pathogenesis, variable complications and treatment. Obesity exacerbates a large number of health related problems, both independently and in association with other diseases. Therefore this topic was chosen and the clinical trial was carried out at Hospital of NIA, Jaipur, India. The aim and objective was to evaluate the effect of Shilajatu (*Asphaltum punjabinum*), Kutaki (*Picrorhiza kurroa*) and Khadir (*Acacia catechu*) in the patients of Sthaulya. 30 patients of Sthaulya were selected and randomly divided into three groups - A, B and C of 10 patients each. 3 in Group B and 1 in Group- A (total 4) were dropped out from the study for irregular follow-ups. Group A (9 patients) of Sthaulya were kept as placebo, controlled and were administered two capsules of 500 mg filled with wheat flour orally twice a day with lukewarm water. Group B (7 patients) were treated with trial drug with warm water. Group C (10 patients) treated with trial drug including controlled diet and regular exercise. The duration of the trial was 3 months with monthly follow up. The data obtained was analyzed using statistical method, One Way ANOVA. Analysis of overall effect of trial drug on subjective and objective parameters of all the three groups revealed that Group C provided highly significant ($p < .001$) reduction in Body weight, BMI, Hip circumference and significant ($p < .01$) difference in waist circumference and other signs and symptoms.

Keywords: Sthaulya, Obesity, Medo dhatu, Agni, Shilajatu, Kutaki, Khadir

INTRODUCTION

Sthaulya corresponds to Obesity. According to Acharya Charak, Sthaulya is discussed under eight undesirable conditions (Ashta Nindita purushas)¹, Shleshma nanatmaja², Samtarpan nimmitaja³, Atinindita⁴, Atibrimhana nimmitaja⁵ and Bahu dosha janita⁶ vikaras. A critical review of the data available in Ayurvedic literature on the subject of Sthaulya brings out an amazing wealth of knowledge about the existing concept with regard to the etiopathogenesis and treatment of obesity and its complications. Now a day, obesity is a common metabolic disorder. It may be associated with varying diseases like Dyslipidemia, Diabetes Mellitus, Myxodema, Artherosclerosis, Cardiovascular diseases (CVD) and Coronary Heart Disease. Ayurveda, expounds its concept to the disproportionate increase of one particular dhatu viz medas and envisaged an obstruction in the srotas (metabolic pathways) resulting in an impairment of agnivyapara (metabolism) which is concerned with intermediary metabolism. Moreover Acharya Sushruta emphasized on metabolic disturbances in the etiopathogenesis of Sthaulya.⁷ Sushruta has indicated that under certain conditions, the predominately sweet substances absorbed from the intestine circulate in an unmetabolised form and this sweet Amarasa is converted into Medas. The latter therefore accumulates in the body and contributes to obesity or Atisthaulya⁷

(Su.su.15/32). Sushruta further states that the condition takes a serious turn due to Avritamarga and therefore it is best to deal with the condition at the etiological level. He points out that in addition to active physical exercise these cases must be treated with Virukshana and Chedaniya substances. Susruta's commentator Dalhana, recommends the use of Virukshana, Medoghana and chedaniya or Srotovisodhaniya dravyas that can clean off the Srotasas that are blocked respectively. Shilajatu (*Asphaltum punjabinum*)⁸, Kutaki (*Picrorhiza kurroa*)⁹ and Khadir (*Acacia catechu*)¹⁰ exert pharmacological actions like vatakaphadoshaghna, Deepan, Pachana, Lekhana (bioscraping)¹¹, Chedan, Medoghana etc. Hence they were selected for the present clinical trial. Acharya Charaka has recommended the use of many effective formulations of Shilajatu in the treatment of various kapha predominant diseases including Sthaulya. Author of Rasratnasamuchchaya described Shilajatu as Medoaghna.¹² Kutaki is described in Lekhaniya mahakashya by Charaka¹³ Lekhaniya dravya do bioscraping of meda and kapha from the obstructed channels. Bhavaprakash states that Khadir is kapha and medohara.¹⁴

Aims and Objectives

- To review the detailed samprapti/etiopathogenesis of sthaulya regarding dosha, dushya, srotas in parlance with modern science.

- To evaluate the efficacy of Shilajatu (*Asphaltum punjabinum*), Kutaki (*Picrorhiza kurro*) and Khadir (*Acacia catechu*) in the management of Sthaulya.

MATERIALS AND METHODS

Study Design

A total of 30 patients of Sthaulya were registered from the OPD and IPD of NIA Hospital, Jaipur, India and randomly allocated into three groups of 10 each. Out of these, 26 patients completed the treatment and rest four patients were dropped out. Study was carried out as per Ethical clearance no- 98/44856.

Group A (n=10) is a control group. The patients of this group were given two placebo capsules thrice in a day with lukewarm water before meal for 3 months. Each capsule was filled with 500 mg wheat flour.

Group B (n=10) Patients of this group were administered trial drug with lukewarm water.

Group C (n=10) Patients of this group were administered trial drug with lukewarm water including balanced and control diet and regular exercise (30 minutes brisk walk).

Diagnostic Criteria

The diagnosis was mainly based on the sign and symptoms as mentioned in the Ayurvedic texts as well as allopathic texts along with weight, BMI, circumference of waist and hip and thickness of skin fold (BMI kg/m²: 18.5-24.9 is normal).

Inclusion criteria

- Patients aged >16 and <65 years.
- Patient with clinical signs and symptoms of Sthaulya as mentioned in the Ayurvedic and Modern literature.
- Patients with BMI >25 (BMI = weight in kg/height in m²).
- Patients with Body Weight >10% of normal body weight in relation to height (according to LIC of India).

Exclusion Criteria

- Patients aged <16 years and >65 years.
- Obesity associated with hypothyroidism, hormonal imbalance, cardiovascular diseases, hemiplegia, diabetes and severe hypertension.
- Females with history of pregnancy and lactation.

Method of preparation of trial drug

The trial drug was prepared in the pharmacy of NIA Jaipur, India. First of all, Shilajatu had purified with Triphala kwath and then prepared into vati of 500 mg each. Second drug is Khadir Ghana Vati 250 mg each, which was prepared by the Ghana of Khadir sara kwatha. Third drug is Kutaki vati 500 mg each, prepared by Kutaki mula churna.

Dose: Shilajatu vati 1 BD and Khadir Ghana vati 1 BD with warm water after meal. Kutaki vati 2 OD with warm water at night.

Duration of Trial: 3 months with monthly follow-ups.

Assessment Criteria

The effect of therapy was assessed on the basis of the improvement in the following subjective/objective criteria.

Subjective Criteria

A multidimensional scoring pattern was adopted for the sign and symptoms of sthauya mentioned in Ayurvedic texts. The score of symptom was assessed before and after the treatment and statistical analysis was undertaken. This assessment was done before starting the treatment and thereafter every month till completion of 3 months course of therapy. The data obtained was analyzed with using statics one way ANOVA.

Objective Criteria

- Weight and BMI was recorded before and after treatment.
- Circumference of hip and waist (cm) were recorded before and after every month.
- The skin fold thickness of the biceps, triceps and middle of the subscapular region was recorded by Vernier calipers.

Assessment of Overall Effect of the Therapy

For the overall assessment of the therapy following categories were taken into consideration.

- Marked improvement: More than 60% improvement noted in sign and symptoms.
- Moderate improvement: 40-60% improvement was noted in the sign and symptoms.
- Mild Improvement: 20-40% improvement was noted in the sign and symptoms.
- Unchanged: No effect in sign and symptoms along with weight.

Observations

- In the present series of 26 patients of Sthaulya, maximum number of patients (40%) were in the age group of 21-30 years, females i.e. 60% and Hindus by religion i.e.100%. 90% were married with 67% of middle socioeconomic status.
- In this series maximum numbers of patients were of Kapha-vata prakriti 47% followed by Kapha-pitta prakriti 30% and vataja pittaja prakriti 17% and maximum number of patients were Vishamagni 80%, maximum number of patients were Krurakoshta.
- 84% patients of this series were vegetarian, 87% were taking excess intake of madhura, guru and shleshmala ahara, 74% patients were living sedentary life style.
- In this study, all the patients showed the symptoms of overweight, chalaudara, sphika 94%, chala stana 77%, Alasya 87% and Atikshudha, Utsahahani 80%, Shawasa 70%.
- Maximum numbers of the patients were with body weight in the range of 70-90 kg 74.07%, above 90 kg 22.22% and 46% with BMI in the range of 25 to 30, 38% in the range of 31 to 35.
- Family history of obesity was recorded in 50% patients.

Table 1: Comparative Effect of Trial Drug on the Signs and Symptoms

Sign and Symptoms	Group A			Group B			Group C		
	BT	AT	Relief	BT	AT	Relief	BT	AT	Relief
Chalaspik	20	20	0.0 %	17	14	17.65%	17	15	11.76%
Chalaudara	21	21	0.0 %	24	15	37.50%	20	15	25.00%
Chalastana	14	14	0.0 %	9	7	22.22%	11	9	18.18%
Ayathopchav	21	21	0.0 %	23	20	13.04%	20	10	50.00%
Nidra	15	15	0.0 %	11	8	27.27%	10	9	30.00%
Utsahahani	10	9	10 %	5	3	40.00%	20	10	30.00%
Sweda	7	7	0.0 %	12	06	50.00%	10	7	22.22%
Karpadangasuptata	9	8	10 %	10	04	60.00 %	11	7	36.36%
Alasya	9	9	0.0 %	7	02	71.43 %	9	6	33.33%
Atishkudha	9	9	0.0 %	8	03	62.50 %	8	6	25.00%
Shwasa	8	7	10 %	16	07	56.25 %	7	3	57.14%

BT: Before Treatment; AT: After Treatment

Table 2: Comparative Effect of Trial Drug on Body Weight

Groups	Mean		SD	SE	t	P
	BT	AT				
Group A	78.944	79.055	.6922	.2307	.481	>0.1
Group B	85.07	82.286	1.912	.723	3.86	<0.01
Group C	84.5	78.85	3.1976	1.1011	5.1311	<0.001

BT: Before Treatment; AT: After Treatment

Table 3: Comparative Effect of Trial Drug on BMI

Groups	Mean		SD	SE	t	P
	BT	AT				
Group A	30.5767	.5811	.239	0.80	-.06	>0.1
Group B	32.5443	31.5057	.699	.264	3.93	<.01
Group C	30.8470	28.8570	1.145	.362	5.50	<0.001

BT: Before Treatment; AT: After Treatment

Table 4: Comparative Effect of Trial Drug on Waist Circumference

Groups	Mean		SD	SE	t	P
	BT	AT				
Group A	107.277	107.055	0.4076	0.136	0.81	>0.10
Group B	103.00	101.28	1.696	0.641	2.441	<.05
Group C	107.45	105.75	2.96	0.935	3.96	<.01

BT: Before Treatment; AT: After Treatment

Table 5: Comparative Effect of Trial Drug on Hip Circumference

Groups	Mean		SD	SE	t	P
	BT	AT				
Group A	114.72	114.66	0.168	.056	1	>0.1
Group B	115.14	112.21	2.224	0.84	3.21	<0.02
Group C	113.55	110.00	2.26	0.174	5.04	<0.001

BT: Before Treatment; AT: After Treatment

Effects of Trial Drug

Group A: Placebo control group provided insignificant change in body weight, BMI and other sign and symptoms of Sthaulya.

Group B: Trial drug showed statistically significant (<0.01) reduction in weight and BMI and (p<0.05) in the symptoms of Sthaulya.

Group C: Trial drug with regular exercise and controlled diet provided statistically highly significantly reduction (p<0.001) in Body weight, BMI, Thickness of skin folds, Hip circumference and significant (p<0.01) reduction in waist circumference.

The overall effect showed that trial drug with exercise and controlled diet provided remarked relief in 50%, moderate improvement in 20% and mild improvement in 20% patients. In this study, 0% patients remain unchanged.

RESULTS AND DISCUSSION

According to Charaka, Excess consumption of high caloric diet like Guru, Snigdha, Madhur rasa foods and sedentary life style create obstruction of Srotas by Medas, due to which Vata dosha viciously circulates in the Koshta and increases the intensity of Jatharagni. This Atyagni rapidly, forcibly digests the food and converts into pichchila upadana Ahara rasa. This ahara rasa is mobilized into the medo vaha srotas and converted into sthaya medo dhatu which begins to accumulate gradually over and above the normal proportions manifesting as Sthaulya or obesity. Sushruta emphasizes the above concept and states that the madhura bhava ama rasa moves within the body, snigdhansha of this anna rasa causes Meda dhatu vridhhi which produces sthulata (excessive stoutness). In pathogenesis of Medoroga, Kapha, Vayu, Meda and Medodhatvagnimandyata are main responsible factors. Most of the symptoms of Medo

Roga comes under the category of Kaphavridhi i.e. Alasya, Gatrāsada, Angagaurava, Nindraadhikya etc. Usually the Medo Rogi belongs to Kaphaja Prakriti who by nature is slow and lethargic in physical activity. Manifestation of Sthaulya proves that it is a kapha predominant condition but involvement of Vata and Pitta cannot be neglected. Symptoms like Atipipasa, Atikshuda, Swedadhikya, Dauragandhya etc. are manifestation of pitta. Vata creates two situations in MedoRoga, first is the state of Avrita Vata which provokes the Agni and ultimately increases the demand for the food and second is inactiveness of Vyana vayu. Vyanvayu is responsible for proper circulation and distribution of Dhatus (C. Ci.15/36). Acharya Sushruta has mentioned MedoRoga as a Dushya dominant disorder. Here rasa, mamsa, meda, majja and shukra dhatus are dushyas as kapha is seated in all these on the basis of ashray-ashrayeebhava. So vitiation of Kapha also leads to vitiation of above Dushyas. Susruta's commentator Dalhana, recommend the uses of Virukshana, Medoghana, Chedaniya and Srotovisodhaniya dravya that can clean off the Srotasas that are blocked respectively by Kapha and Medas. Trial drugs are katu, tikta, kashaya in rasa, katu in vipaka and laghu in guna due to this it is helpful to reduce kapha and meda dhatu. Shilajatu is medohara by chedan karma, Khadir is a virukshana and medoghna dravya and Kutaki is lekhan dravya. Due to these pharmacological properties all the trial drugs¹⁵ exert chedan, lekhan and soshana karma combindly i.e scraping off the abnormally accumulated meda dhatu and kapha from srotas and channelizes the obstructed srotas. Shilajatu contains fulvic acid which effectively maintains the optimum energy metabolism and most of the excess calories consumed are burnt off and not converted into fat¹⁷. Acharya Charak recommended Apatarpan Chikitsa as main line of treatment for santarpan janit vikar such as Sthaulya and all the above karmas are come under Apatarpan Chikitsa.¹ In the present work, 30 patients who fulfilled the diagnostic criteria of Sthaulya were selected. Out of which 4 patients had left the treatment at different stages. The remaining 26 patients, 9 patients in group A (Control), 7 patients in group B (drug treated) and 10 patients in group C (drug with exercise treated group) completed the trial whose data is presented below. Comparison of the results of three groups showed that (trial drug with regular exercise) i.e. Group C provided highly significant improvement in body weight, BMI, Circumference of hip and waist and other symptoms of sthauilya as Utsahahani, Angagaurava, Nindraadhikya, Gatra sada in comparison to group B and group A (Table 1, 2, 3, 4, 5). Group B imparted comparatively mild significant reduction in the body weight, BMI, Circumference of hip and waist and other symptoms of sthauilya as Utsahahani, Angagaurava, Nindraadhikya, Gatra sada as to Group A. Overall assessment of the results of all the three groups showed that Trial drug with regular exercise and control diet provided best improvement in most of the signs and symptoms related to sthauilya.

CONCLUSION

Sthaulya is shleshma nanatmaja, Samtarpan nimmitaja, Atinindita, Atibrimhana nimmitaja and Bahu dosha janita vikaras. It is a Medodhatwagni mandya vikara and is one the important predisposing factors for various conditions like Diabetes, Hypertension, IHD, CVA etc. The clinical trial of drug Shilajatu, Kutaki and Khadira along with diet and life style management has shown significant results on various signs and symptoms and objective parameters like body weight, BMI and Waist circumference etc.

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