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Clinical Research

Clinical efficacy of *Shilajatu* (*Asphaltum*) processed with *Agnimantha* (*Clerodendrum phlomidis* Linn.) in *Sthaulya* (obesity)

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Abstract

Obesity is defined as the condition in which excessive amount of fat is accumulated in the body. Classical Ayurvedic texts describe eight types of despicable designated as '*Nindita purusha*' including *atisthaulya*. Corpulent people are characterized by short in longevity, slow movement, difficult to indulge in sex, weak, emission of bad body odor, profuse perspiration, excessive hunger and excessive thirst. Sixty to seventy percent of cardiac patients die of obesity and contribute to develop coronary artery disease, diabetes mellitus, hypertension, hyperlipidaemia. In the present study, 66 patients of obesity were treated with *Shilajatu* processed with *Agnimantha*. After complition of therapy, 5.09 ± 0.24 kg and 2.06 ± 0.10 kg/m^2 reduction of body weight and body mass index, respectively were noted. The result was found to be statistically highly significant (P<0.001). No adverse effects were observed in any of the treated patients.

Key words: *Asphaltum punjabianum*, *Clerodendrum phlomidis*, *Obesity*, *Shilajatu*, *Sthaulya*

Introduction

An excess accumulation of energy in the form of body fat >25% in males and >30% in females is considered as obesity which is becoming a global health problem.[1] It is the most common nutritional disorder in affluent society. The weight charts for men and women according to their height (BMI) are only rough indications of the state of overweight or obesity. Obesity can be compared with '*Medoroga*' in *Ayurveda*[2] and said that, comparatively it is easy to help an underweight person rather than a overweight person. The overweight/obese problem can either be due to an actual increase in fat component or due to malfunctioning. Body is made of seven *Dhatus* (tissue) but obese are nourished excessively by *Meda Dhatu* (fatty tissue) and other remaining tissues get malnourished, *Kapha* gets accumulated in between. When *Kapha* increases in abnormal fashion, fat metabolism is hampered and persons become obese.[3]

According to latest estimates, the prevalence of overweight and obesity in the United States makes obesity a leading public health problem with highest rates of obesity in the developed world.[4] During 1980 to 2002, obesity has found doubled in adults and overweight being tripled in children and adolescents.[5] Currently, about 119 million or 64.5% of US adults are either overweight or obese and continue to rise in United States. The health service of England predicts that >12 million adults and 1 million children will be obese by 2010, if no action is taken.[6] Obesity, an increased fat content in the body, is now a major health problem in India; even under weight Indians have higher fat content than overweight foreigners. Recent survey shows 60% middle aged, working class Indians in Mumbai were overweight. In another survey, 30% children in Delhi's elite schools were in the same category.[7] Doctors are also far more obese with 55.5% had high waist circumference against 35.8% in the general population.[8] Overweight also contributes to develop diabetes mellitus, hypertension, hyperlipidaemia, kidney and gall bladder disorder. It has implicated an increased incidence of some types of cancer. Persons with over weight suffer from osteoarthritis menstrual irregularities, bad body odor, become common targets of comments and taunts which can affect psychological health of the person.

Many drugs like appetite suppressants, HMG-co reductase inhibitors, pancreatic lipase inhibitors, S-NRI etc. and bariatric surgery have not been able to control the increasing number of obese in the society. Moreover, modern drugs have limitations in their actions and are not free from side effects. On the other hand, the physicians of Indian System of Medicine are treating this condition for thousands of years with no remarkable side

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effects. Ayurvedic treatment of a disease consists of salubrious use of drug, diet and healthy life style. Medicinal preparations are single or complex mixtures, based on plant, animal and mineral products. Many cost-effective Indian medicinal plants have come after scientific scrutiny since the middle of nineteenth century, although in sporadic fashion having no remarkable side effects.[9]

The present study deals with the classical herbo-mineral compound containing *Shilajatu* (*Asphaltum punjabianum*) and *Agnimantha* (*Clerodendrum phlomidis* Linn.) indicated for *Sthaulya*.[10]

Aims and objectives

To evaluate therapeutic efficacy and adverse effects of *Shilajatu* processed with *Agnimantha*.

Materials and Methods

66 patients of *Sthaulya* were registered from OPD and IPD of I.P.G.T and R.A, hospital, Jamnagar fulfilling the clinical diagnostic criteria of *Sthaulya* based on Ayurvedic and modern parameters. Out of 66 registered patients, 53 patients completed the treatment and remaining 13 patients dropped out at different intervals. Five patients were migrated to another place for job, five patients had poor compliance and were unable for regular check up, one female patient was conceived, and two patients had lack of faith in Ayurvedic medicine.

Inclusion criteria

The patients of *Sthaulya* (obesity) were selected after taking short history from the O.P.D and I.P.D of I.P.G.T and R.A, hospital. Patients between the age of 20 to 60 years were selected. The patients selected for clinical trial were according to signs and symptoms of *Sthaulya* described in Ayurvedic texts and modern parameters [BMI kg/m^2: 18.5-24.9 is normal; 25-29.9 over weight, 30-34.9 obesity class-I, 35-39.9 class II] were also considered. Thus cases between BMI>25 kg/m^2 and <40 kg/m^2 were included.

Subjective criteria

A proforma incorporating all clinical aspects mentioned for *Sthaulya* was prepared. Detailed medical history and thorough clinical examination was done. The signs and symptoms of *Sthaulya* mentioned in *Ayurveda* were assigned a suitable scoring pattern to assess the condition of the patients before and after the completion of therapy [Table 1].

Objective criteria

Assessment of patients by B.M.I (body mass index)=weight (in kg)/height (m^2), body circumference (cm), skin fold thickness (cm), and laboratory investigations carried out before and after treatment include: a) routine hematological investigations including Hb%, TC, DC, ESR; b) routine urine analysis; c) routine stool analysis; d) biochemical examinations like blood sugar (fasting and post prandial), lipid profile (serum cholesterol, serum HDL, serum LDL, triglyceride), blood urea and serum creatinine, serum T_3, T_4, TSH (limited and selected cases to rule out abnormal thyroid function).

Exclusion criteria

Patients below the age of 20 years and above the age of 60 years,

Table 1: Scoring pattern of *Sthaulya*

Scoring pattern	Grading
Bharavriddhi (rise of body weight)	
BMI - <27 kg/m²	0
BMI - 27-29.9 kg/m²	1
BMI - 30-32.9 kg/m²	2
BMI - 33-35.9 kg/m²	3
BMI - >36 kg/m²	4
Angachalatva (pendulous movement of body parts)	
Absence of *Angachalatva*	0
Little visible movement after fast movement	1
Little visible movement after moderate movement	2
Movement after mild movement	3
Movement even after change of posture	4
Angagaurava (heaviness of body)	
Absence of *Gaurava*	0
Occasional heaviness	1
Persistent heaviness relieved after rest	2
Persistent heaviness not relieved after rest, can do normal daily work	3
Persistent heaviness cannot do normal daily work	4
Swedadhikya (excessive perspiration)	
Sweating after heavy work	0
Sweating after little work	1
Profuse sweating after heavy work	2
Profuse sweating after minimum work	3
Sweating even in resting condition	4
Atipipasa (excessive thirst)	
Normal thirst	0
Upto 1 l excess intake of water	1
1 to 2 l excess intake of water	2
2 to 3 l excess intake of water	3
More than 3 l excess intake of water	4
Gatra Daurgandha (bad body odor)	
Absence of bad smell.	0
Occasionally bad smell to close areas difficult to suppress with deodorants.	1
Persistent bad smell felt from long distance and not suppress with deodorants.	2
Persistent bad smell felt from long distance, even intolerance to the patient himself.	3
Ati Kshudha (excessive hunger)	
Unwilling for food but could take the meal.	0
Willing toward only most liking food and not others.	1
Willing toward only one among *Katu*/*Amla*/*Lavana*/*Madhura* food stuffs.	2
Willing toward some specific *Ahara*/*Rasa*/*Vishesa*	3
Equal willing toward all the *Bhojjya Padartha*.	4
Kshudra Shvas (dyspnoea on exertion)	
Dyspnoea after heavy work but relieved soon and up to tolerance.	0

(Contd...)

Table 1: (Continued)

Scoring pattern	Grading
Dyspnoea after moderate work but relieved late and up to tolerance	1
Dyspnoea after little work but relieved late and up to tolerance	2
Dyspnoea after little work but relieved soon and beyond tolerance.	3
Dyspnoea in resting condition.	4
Utsaha Hani (lack of energy)	
No *Alasya*	0
Doing work satisfactorily with late initiation.	1
Doing work unsatisfactorily with lots of mental pressure and late in time.	2
Not starting any work in his own responsibility, doing little work very slowly	3
Dyspnoea in resting condition.	4
Maithuna Hani (loss of libido)	
Unimpaired libido and sexual performance.	0
Decrease libido but can perform sexual act.	1
Decrease libido but can perform sexual act with difficulty.	2
Loss of libido and cannot perform sexual act.	3
Snigdhangata (unctuousness of body)	
Normal *Snigdhata*	0
Oily lusture of body in summer season	1
Oily lusture of body in dry season	2
Excessive oily lusture of body in dry season can be removed with difficulty.	3
Persistent and profuse slickness all over body.	4
Daurbalya (weakness)	
Can do routine exercise	0
Can do moderate exercise without difficulty	1
Can do only mild exercise	2
Can do even mild exercise with very difficulty	3
Can't do even mild exercise	4

endocrine disorders like diabetes mellitus, hypothyroidism, Cushing's syndrome and obesity with cardiac problems like hypertension, ischemic heart disease, cardiac failure were excluded. *Sthaulya* with pregnancy and with other significant associated illness, patients taking cortico-steroids, oral contraceptive pills and B.M.I-40 kg/m^2 and above i.e. class –III extremely high obesity and severe complicated cases were also excluded. Written consent for clinical trial was duly taken from each patient and they were free to withdraw any time from study as per their wish, they were told. This study was cleared by the Institutional Ethics Committee.

Method of preparation of the trial drug

Purified *Shilajatu* was triturated seven times in *Svarasa* (fresh juice) of *Agnimantha* (*Clerodendrum phlomidis Linn.*) and capsules were prepared of 500 mg each. Both the components of the trial drugs were procured from the Pharmacy, Gujarat Ayurved University and duly identified. *Agnimantha* leaves were washed with clean water and juice was prepared. *Bhavana* with juice was given for seven times to *Shilajatu*. For seven *Bhavana*, total 30 days period was required. After proper drying, it was finely powdered and 500 mg capsules were filled. It was given in a dose of two capsules twice daily for 10 weeks with luke warm water. The medicine was packed in polythene pouch each containing 56 capsules, to fulfill the requirement of two weeks for each patient.

Dose: Two capsules twice daily (each of 500 mg) before meal
Duration: 10 weeks
Anupana: Luke warm water

Follow up

Patients have been examined for follow up for one month at the interval of 15 days to record the effect of therapy.

Statistical analysis

The information gathered on the basis of observation made about various parameters was subjected to statistical analysis in terms of mean values, standard deviation (SD), standard error (SE). Paired '*t*' test was carried out at $P<0.05$, <0.01 and <0.001. The obtained results were interpreted as: $P>0.05$ considered as insignificant, <0.01 to <0.05 considered as significant and <0.001 is highly significant and the P values are adapted from java script.[11]

Observations and Results

The demographic data of 66 registered patients of obesity revealed that maximum patients (45.45%) had *Kapha-Pittaja Deha Prakriti* followed by 42.42% *Kapha-Vataja Deha Prakriti*. The Prakriti of each patient was decided as per the information given in Tables 2 and 3. Maximum (36.36%) patients belonged to age group of 20-30 years followed by 34.85% of 31-40 years and females (80.30%). Religion-wise maximum patients were Hindus (68.18%). Majority of patients were housewives (71.21%), maximum patients were from urban area (90.90%) and from middle-income group (56.06%). Maximum patients (43.93%) had history of sedentary type of work, indulge vegetarian diet (65.15%) and had consumed (45.45%) *Sarvarasa* (all type of taste includes sweet, sour, salty, pungent, bitter and astringent). Maximum patients had consumed *Madhur Rasa* (sweet taste) in their daily diet (60.60%).

Discussion

The data shows a statistically highly significant relief was found in *Bharvriddhi*, *Angachalatva*, *Angagaurava*, *Swedadhikya*, *Atipipasa*, *Gatradaurgandha*, *Atikshudha*, *Kshudra Shvas*, *Utsahahani*, *Atinidra*, *Snigdhangata*, *Daurbalya* while improvement in *Maithuna Hani* was statistically insignificant [Table 4]. Disease *Sthaulya* originates due to consumption of *Kapha Vriddhikara Ahara* (diet), *Vihara* (regimen) and *Manasa* (psychological) *Nidana* (causes). These factors derange *Jatharagni* (digestive juices, enzymes, hormones) causing *Ama* (metabolic toxins) production, which results in *Medodhatvagni-Mandya* (improper production of anabolic enzymes of fatty tissue). This condition leads to excessive growth and accumulation of *Medo Dhatu*, causing the

Table 2: Main subjective features of various *Prakriti*[12]

Features	*Vata Prakriti*	*Pitta Prakriti*	*Kapha Prakriti*
Appetite	Irregular	Sharp	Low
Bowel habit	Constipated and irregular	Unformed faces	Regular and well formed feces
Temper	Very easily excited	Excited, may become violent	Slowly excited but does not give up revenge once excited
Reactive power	Very quick	Quick	Slow but steady
Sexual desire	Meager	Moderate	Abundant
Types of dreams	Flying in sky, jumping, running, climbing trees	Blazing fire, lightening, golden sun, struggle, wars	Water, lakes, river, birds, swan, cloud, ocean, romance
Desire for	Warm article	Cold article	Warm article

Table 3: Main objective features of various *Prakriti*[12]

Features	*Vata Prakriti*	*Pitta Prakriti*	*Kapha Prakriti*
Body frame	Long or short but lean	Medium size	Large, plump, fleshy and fatty
Skin	Blackish, rough, cracking	Fair, reddish with moles, freckles	Fair and whitish, soft and smooth
Body weight	Less or lower side of normal range	Average	Excessive, tendency for obesity
Hairs	Scanty and rough	Scanty, soft, dry, tough, tendency for premature graying, falling and baldness	Plenty, smooth, soft, black, thick, long with firm roots
Face	Nonspecific	Delicate with wrinkles	Attractive, glossy
Body color	Blackish	Coppery	Fair, whitish, unctuous, glossy
Lips	Dry and blackish	Coppery	Unctuous and moist
Tongue	Darkish	Coppery	Clean
Activity	Quick, light and active and frequently moves body parts	Moderately active body parts	Slow
Sleep	Scanty and interrupted	Moderate and sound	Deep and excessive

disease *Sthaulya*. *Agnimantha* processed with *Shilajatu* is having *Katu* (*pungent*), *Tikta* (*bitter*), *Kashaya* (*astringent*) *Rasa*, *Katu Vipaka* (post digestion effect), *Ushna Virya* (hot in potency), *Kapha-Vata Shamaka*, *Lekhaniya* (bio scraper), *Chhedaniya*, *Yogavahi* (bio enhancer) *and Rasayana* (rejuvenation) properties, which normalize the state of *Agni* (energy). Thus, regulated *Jatharagni* checks the excessive growth and accumulation of fatty tissue. *Shilajatu* amplifies the benefits of other herbs by enhancing their bio-availability.[13] It helps to transport nutrients deep into the tissue, removes deep-seated toxins, improves memory and ability to handle stress, reduces recovery time in muscle, bone and nerve injuries, stimulates the immune system and reduces chronic fatigue.[13] The Student '*t*' test (paired) showed statistically highly significant results by conventional criteria ($P<0.001$) on body weight and body mass index (BMI) [Table 5]. The decrease in various body circumferences were statistically highly significant by conventional criteria ($P<0.001$) in Student's paired '*t*' test [Table 6]. *Agnimantha* lowers blood cholesterol level.[14] *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 fat.[15] Reduction was noticed in skin fold thickness i.e. in biceps (11.01%), triceps (11.0%), scapular (9.69%), abdominal (11.23%) and thigh (8.88%) which was highly significant by conventional criteria in paired '*t*' test ($P<0.001$) [Table 7]. Total body fat percentage is the total weight of the person's fat divided by the person's weight and reflects both essential fat and storage fat. Essential fat is necessary for maintenance of life and reproductive functions, and storage of fat consists of fat accumulation in adipose tissue, part of which protects internal organs in the chest, abdomen etc;[16] and exist various anthropometric methods for estimating body fat such as circumferences of various body parts or thicknesses of skinfolds.[17]

The reduction was observed in PPBS (1.66%), serum cholesterol (3.31%), serum LDL (4.76%) and serum triglyceride (6.36%). The serum cholesterol decrease was quite significant ($P<0.05$) whereas reduction in PPBS, serum LDL and serum triglyceride was insignificant ($P>0.05$). The increase in serum HDL-cholesterol was observed 1.83%, though statistically insignificant ($P>0.05$) [Table 8]. The above data reveals that the drug has not shown encouraging results in respect to various biochemical parameters except serum cholesterol. *Shilajatu* has proven to possess liver protecting effects and lowers cholesterol and triglyceride levels. It helps in reducing accumulation of fatty substances and cholesterol in the arteries and prevents LDL cholesterol from reacting with free radicals and hence preventing their accumulation in the arteries.[18] 7.72% reduction of body fat was observed which was statistically highly significant by conventional criteria in two tailed paired '*t*' test ($P<0.001$), while increased level of BMR was 7.62%, which was statistically highly significant ($P<0.001$) in paired '*t*' test. *Shilajatu* has been used as a strong aphrodisiac for men since ancient times in India. It counteracts free radicals and arrests degenerative disorders and maintains the equilibrium of energy metabolism in the body.[19] When total effect of the treatment on subjective and objective parameter was taken into consideration, it was revealed that marked improvement was observed in 9.43% cases, moderate improvement in 56.61%, mild improvement in 26.42% cases whereas 7.54% cases remained unchanged.

Conclusion

Agnimantha processed with *Shilajatu* is found to be a potent. Moreover, from pharmacovigilance point of view, no clinical adverse effects have had been observed in any of the patients during the study.

Table 4: Response of treatment on subjective criteria

Clinical features	*n*	Mean score		% of relief	SD	SE	*t*	*P*
		BT	AT					
Bhar Vriddhi	53	2.43	1.92	20.93	0.50	0.07	7.35	<0.001
Angachalatva	20	2.1	1.1	47.62	0.65	0.14	6.89	<0.001
Angagaurava	28	1.75	0.07	95.92	0.47	0.09	18.68	<0.001
Swedadhikya	36	1.80	0.28	84.62	0.74	0.12	12.45	<0.001
Ati Pipasa	31	2.29	0.42	81.69	0.76	0.75	2.51	<0.001
Gatradaurgandhya	14	1.28	0.36	72.22	0.62	0.16	5.64	<0.001
Atikshudha	21	3.04	0.81	73.44	1.09	0.24	9.40	<0.001
Kshudrashvasa	38	2.07	0.63	69.62	0.55	0.09	16.08	<0.001
Utsahahani	10	1.1	0.2	81.82	0.32	0.1	9.00	<0.001
Maithunahani	5	2	1.2	40.00	0.84	0.37	2.13	>0.05
Atinidra	20	2.6	0.2	92.31	1.14	0.26	9.39	<0.001
Snigdhangata	11	1.45	0.18	87.50	0.47	0.14	9.0	<0.001
Daurbalya	33	1.88	0.12	93.55	0.43	0.26	9.39	<0.001

BT - Before treatment, AT - After treatment, SD - Standard deviation, SE - Standard error

Table 5: Response of treatment on weight and BMI

Parameters	*n*	Mean weight and BMI		% of relief	SD	SE	*t*	*P*
		BT	AT					
Weight (kg)	53	82.34	77.25	6.19	1.82	0.25	20.42	<0.001
BMI (kg/m^2)	53	33.30	31.24	6.19	0.73	0.10	20.47	<0.001

Table 6: Response of treatment on organ measurement

Organ	*n*	Mean measurement (cm)		% of relief	SD	SE	*t*	*P*
		BT	AT					
Chest	53	104.19	100.96	3.09	1.90	0.26	12.36	<0.001
Abdomen	53	101.61	97.18	4.36	2.15	0.29	15.04	<0.001
Buttocks	53	116.18	112.80	2.91	3.12	0.43	7.87	<0.001
Thigh	53	55.29	52.96	4.21	1.85	0.25	9.18	<0.001
Shank	53	38.83	37.76	2.75	1.06	0.15	7.32	<0.001
Arm	53	33.61	31.45	6.43	1.03	0.14	15.31	<0.001

Table 7: Response of treatment on skin folds thickness

Skin fold at	*n*	Mean measurement (cm)		% of relief	SD	SE	*T*	*P*
		BT	AT					
Biceps	53	2.40	2.14	11.01	0.14	0.01	14.14	<0.001
Triceps	53	2.97	2.64	10.99	0.20	0.02	11.87	<0.001
Scapular	53	2.98	2.69	9.69	0.17	0.02	12.32	<0.001
Abdomen	53	3.19	2.83	11.23	0.17	0.02	15.42	<0.001
Thigh	53	3.08	2.81	8.88	0.16	0.02	12.47	<0.001

Table 8: Effect on biochemical parameters

Parameter (mg%)	*n*	Mean values (mg/dl)		% of relief	SD	SE	*t*	*P*
		BT	AT					
PPBS	44	107.70	105.91	1.67	17.51	2.64	0.68	>0.05
Serum cholesterol	53	179.62	173.68	3.31	24.65	3.39	1.76	<0.05
Serum HDL	53	44.15	44.96	1.84	10.41	1.43	0.57	>0.05
Serum LDL	53	111.61	106.29	4.76	25.28	3.47	1.53	>0.05

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हिन्दी सारांश

स्थौल्य रोग में अग्निमन्थ भावित शिलाजतु का चिकित्सकीय अध्ययन

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स्थौल्य वर्तमान समय की एक भयानक समस्या है। आरामतलब, अपरिश्रमी, निद्राशील जीवनशैली के कारण समाज में स्थौल्य रोगियों की संख्या में निरंतर वृद्धि हो रही है। आयुर्वेद संहिताओं में इसे अष्टनिंदित पुरूष के अंतर्गत वर्णित किया है। स्थूल पुरूष में आयुह्रास, कृच्छ्रव्यवायता, दौर्गन्ध, स्वेदाधिक्य, अतिक्षुधा, अतिपिपासा आदि लक्षण पाये जाते हैं। ६०%–७० % हृदय रोगियों की मृत्यु का कारण स्थौल्य है। इसके परिणाम स्वरूप – मधुमेह, उच्चरक्तचाप, हृदय रोग, रक्तगत वसाधिक्य आदि रोग होते हैं। अग्निमन्थ भावित शिलाजतु की औषध क्रियाशिलता जानने के लिये एक चिकित्सकीय अध्ययन किया गया जिसके द्वारा शरीर भार एवं विभिन्न स्तर पर शरीर में वसा की घनता में कमी पाई गई।