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## COMPARATIVE CLINICAL EVALUATION OF SIHIN MIDI (PREMNA INTEGRIFOLIA LINN) DECOCTION AND GUGGULU CAPSULE IN ATHISTHAULYA (OBESITY)

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### ABSTRACT

*Sihin Midi* (*Premna integrifolia*, Family – Verbenaceae) is an important medicinal plant and its barks of the root is used for the treatment of obesity and hyperlipidemia in traditional physicians in Sri Lanka. **Objective:** This study was designed to compare the effectiveness of *Sihin Midi* decoction with standard medicine-Guggulu capsule for the treatment of *athisthaulya*. **Method:** Sixty patients (18 – 60 yrs of both sexes) with *athisthaulya* (BMI > 30 Kg/m<sup>2</sup>) were selected using open prospective method from the outpatient department at Ayurveda hospitals in Borella and Molligoda, Sri Lanka and divided in to two groups (n = 30 x 2). They were diagnosed and recorded the weight, Body Mass Index, severity of the symptoms, and values of serum cholesterol and serum triglyceride at the beginning and the end of the study. Group 1 was treated with *Sihin Midi* decoction (120.0 ml) twice daily and Group 2 was treated with *Guggulu* capsules (250.0 mg) twice daily for four weeks. **Results:** At the end of the treatment, study group 1 showed significant weight reduction,  $p \leq 0.05$  improvement in Body Mass Index and significant improvement shown in symptoms of *athisthaulya* comparable to group 2. Study confirms *Sihin Midi* decoction is significantly effective in the management of *athisthaulya* with no possible adverse effect, and its use in traditional medicine has been scientifically validated.

**KEYWORDS:** *athisthaulya*, obesity, *Sihin Midi*, *Premna integrifolia*.

## INTRODUCTION

Obesity is one of the most threatening health problems of the present era as it associated with many diseases and reached globally epidemic proportions. As per modern view, it is a medical condition in which excess body fat has accumulated to the extent that it may have an adverse effect on health, leading to reduced life expectancy and increased health problems.<sup>[1]</sup> Obesity defined as an abnormal growth of adipose tissue in the body, due to an enlargement of fat cell size (hypertrophic obesity) or increase in fat cell number (hyperplastic obesity) or a combination of both. Obesity present when more than 20 % of body weight is due to fat in men and more than 25% in women.<sup>[2]</sup> The WHO defines obesity as a BMI is greater than or equal to 30 kg/m<sup>2</sup> and overweight (pre-obese) is greater than or equal to 25 kg/m<sup>2</sup>.<sup>[3]</sup> Obesity is associated with more than thirty medical conditions, and scientific evidence has established a strong relationship with fifteen of those conditions. It is the most common causative factor for various diseases, specially cardiovascular diseases (mainly heart diseases and stroke; were leading cause of death in 2012), type II diabetes mellitus, musculo skeletal disorders (especially osteoarthritis), certain types of cancers (endometrial, bresat, ovarian, prostate, liver, gall bladder, kidney, colon), hypertention, breathing difficulties during sleep. It is not only a health risk, but also a major nutritional disease. Thus, mortality and morbidity are more in obese person compared to others.

This obesity condition can be corelated to *athisthaulya* in Ayurveda. *Athisthaulya* was mentioned since very early times in various Ayurveda classical texts, Acharya Charaka described *athisthaulya* is one among eight types of persons who did not have ideal health and they are termed as '*ashtau nindita purusha*'.<sup>[4]</sup> In Caraka Samhitha *athisthaulya* defined as a person whose excessive and abnormal increase of fat tissue (*medo dhatu*) along with muscle tissue (*mansa dhatu*) will lead to buttocks (*sphick*), abdomen (*udara*) and breast (*sthana*) to become pendulous during movement and strength is rendered disproportionate with his physical growth.<sup>[5]</sup> The balance of *vatha*, *pitha* and *kapha* especially *samana vatha*, *pachaka pitha* and *kledaka kapha* along with depletion of *medodhatu* by increasing *medodhatvagni* is main goal of treatment in *athisthaulya*.

*Sihin Midi* plant botanically identified as *Premna integrifolia* (Family-Verbenaceae), known as '*Agnimantha*' in Ayurveda, and mentioned for management of *athisthaulya*. *P. integrifolia* is a large thorny deciduous shrub or small tree reaching 9.0 m height, which grows along the seacoasts of Sri Lanka, Bangladesh to Thailand, etc.<sup>[6]</sup>

*Sihin Midi/Agnimantha* roots directly used as medicine for obesity in many Ayurvedic authentic texts. Acharya Charaka<sup>[7]</sup> Acharya Vagbata,<sup>[8]</sup> Acharya Chakradatta<sup>[9]</sup> has described *Agnimantha Swarasa* in treatment of *athisthaulya* along with *Silajatu*. In *Susrutha Agnimantha* is included in *Varunadi gana* for remove *kapha* and *medas*.<sup>[10]</sup>

According to literature, *Agnimantha* has *katu*, (pungent), *thikta* (bitter), *kashaya* (astringent) tastes which led to reduce *kapha dosha* and *medo dhathu* in the body. Also, it has been observed that *sukshma* (fineness), *ruksha* (rough /nonunctuosness) and *lagu* (lightness) *guna* (quality), *ushna virya* (hot in potency) and *katu vipaka* (pungent after effect). *Sihin Midi / Agnimantha* has been observed for specific *karma* (actions ) such as *kapha vatha shamaka* (pacify *kapha* and *vatha*), *deepana* (improves appetite), *pachana* (stimulate digestion), improves *agni* (improves metabolism), removes *ama*, *anulomana* (carminative), *medorogahara* (alleviating fat in the body), *shothahara* (alleviating oedema), *vedana sthapana* (analgesic), *raktha shodaka* (purify of blood), *hriduttejaka* (heart stimulating) and *pramehaghna* (alleviating conditions of poyurea and abnormal urine).<sup>[11]</sup> Dosage forms of *Sihin Midi (Agnimantha)* are *Choorna* 3.0 g, *Swarasa* 10.0 ml – 20.0 ml and *Kwatha* 10.0 – 100.0 ml. *Sihin Midi* included drug formulations are *Dashamula kvatha*, *Dasamoola arishta*, *Dashamula churna*, *Agnimantha moola kalka*, *Agnimantha kashaya*, *Narayana taila*, *Chavaanaprashavalehaya*, *Ahiphenasava*, *Karpura rasa*, *Vajra kapota rasa*, *Mushakadya taila*, *Nidrodaya vati*, and *Kamini vidravana rasa*. *Premnine*, *Ganiarine* and *Ganikarine* were found as chief active principles present in *P. integrifolia*.<sup>[11]</sup> Roots of the plant have *premnine*, *beta-sitosterol*, *triterpenes*, *polyphenols*, *n-octacosanol* and *n-triacontanol* along with some inorganic salts. The roots contain a yellow colouring matter, *tannin* and an essential oil which is used in Sri Lanka for the treatment of colic. An antibiotic of phenolic nature has been isolated from the fresh root bark. It was found to be active against the Gram – positive organisms.<sup>[12]</sup> *Rajendran and Krishnakumar*,<sup>[13]</sup> comment on *Premna serratifolia* Linn. did not produce any toxic symptoms nor mortality up to the dose level of 2000.0 mg/kg body weight in rats, and hence the extract was considered to be safe and non-toxic. Root bark of *Agnimantha (Premna obtusifolia* Linn) shows significant therapeutic value in obesity, showed remarkable decrease in BMI, triglyceride, cholesterol - HDL ratio, and LDL -HDL ratio after nine months of treatment and no adverse effect of the drug has been recorded. <sup>[14]</sup> Traditional phycians in Sri Lanka, decoction of the roots of *Sihin Midi (SMD)* has been used for the treatment of obesity and hyperlipidemea. To the best of our knowledge, no work has been reported the effectiveness of SMD for the treatment of obesity and hyperlipidemea

though it is used in traditional medical system in Srilanka. The present study was focused to compare the effectiveness of *Sihin Midi* decoction (SMD) with standard medicine, *Guggulu* capsule for the treatment of *athisthaulya*.

*Guggulu* is the main ingredient of anti-obese drugs used in Ayurveda, which has weight reducing and lipid lowering properties. Acharya Sushruta mentioned *Guggulu* is the best drug for treatment of *medoroga* (fat disorders).<sup>[15]</sup>

## MATERIALS AND METHODS

### Materials

Fresh roots of *Sihin Midi* were purchased as bulk samples from Putlam area on July 2014. Root samples were identified and were authenticated by the Department of Drvya Guna Vingnana, Institute of Indigenous Medicine, University of Colombo. The root samples of *Sihin Midi* were identified also from Herbal Technology Section, Industrial Technology Institute.

### Preliminary preparation of raw materials

After removal of all foreign matters of roots, were washed with running water then was cut in to small pieces and was dried under shade conditions for 30 days to avoid chemical changes. The dried samples were coarsely powdered using grinding machine, was stored in polythene bags at room temperature and was used for trial drug.

*Shuddha Guggulu* capsules (GC) which was used as positive control in this study was obtained from drug manufacturing company.

*Athisthaulya* patients were selected from the Out Patient Department (OPD) at Ayurveda hospitals in Borella and Molligoda.

### Ethical clearance

Ethical approval for the clinical trial was granted by the Ethics Review Committee of the Institute of Indigenous Medicine, University of Colombo, Rajagiriya under Registration number of ERC 14/25.

**Preparation of test drug - *Sihin Midi* decoction (SMD)**

Coarsely powdered 60.0 g of SMD and 1920.0 ml of water was added to earthen pot and was boiled over moderate fire until reduced to 240.0 ml of the volume. This gives the conventional dose for an adult which is 240.0 ml per day.

**Inclusion criteria**

Patients having any one of the following criteria will be subjected to include in this study.

1. Individuals of both sex aged between 18 – 60 years with obesity (BMI > 30 Kg/m<sup>2</sup>)
2. Individuals diagnosed with hyperlipidemia (with one or more of the following lab parameters: serum cholesterol exceeded 260.0 mg/dl after 12 hours of fasting or with LDL more than 160.0 mg/dl or with HDL less than 40.0 mg/dl).

Above patients if willing to sign on consent form and to participate in the study will be included in this clinical trial.

**Exclusion criteria**

Subjects with diabetes, hypertension, endocrinal disorders and patients with other complications were not selected. Pregnancy, lactation and subjects of extremes of age i. e. below 18 years or above 60 years also not selected.

**Study design**

Comparative clinical trial was conducted using open prospective method to study the effectiveness of SMD and GC in the treatment of *Athisthaulya*.

*Athisthaulya* patients were selected from the Out Patient Department (OPD) at Ayurveda hospitals in Borella and Molligoda. *Athisthaulya* patients (n = 60) on diet control between 18-60 years age of both sexes who volunteer to participate were enrolled. All the patients were selected by using open prospective method. Once diagnosed of *athisthaulya*, it made as the basis of Ayurvedic symptoms. A detailed performa prepared for this study was used to record the signs and symptoms, complete history of disease, family history, and the history of any other disease. Weight, signs and symptoms, values of lipid profile (> 260 mg / dl), LDL (> 160.0 mg /dl) with HDL (< 40.0 mg /dl) were also measured. Those were measured at the beginning of the study and the end of the study. Written consent was obtained from the each of the selected patients and they were divided in to two groups (n = 30 x 2). Group 1 (n=30) was treated with SMD (120.0 mL) twice daily for four weeks. Group 2 (n=30) was treated

with GC (250.0 mg) twice daily for four weeks. Serum lipid profile - total serum cholesterol, triglycerides, HDL and LDL were done before and after treatments. Body weight (Kg) and height (cm), Body Mass Index (BMI), waist circumference, hip circumferences and Skin fold thickness were measured for anthropometric measurements.

### Statistical analysis

Bio statistical and aetiological data gathered from the patients was subjected to statistical analysis using the statistical package SPSS and using Wilcoxon signed Ranks Test. All the data of these groups were presented as mean  $\pm$  SD. Significant differences between the two groups were analyzed. Values considered statistically significant at  $p \leq 0.05$ .

### RESULTS AND DISCUSSION

According to clinical study, patients were aged within the range of 18 to 60 years. Majority of patients i.e. 48 % belong to the age group 41 – 50yrs and middle age group occurrence was most common. According to western medicine most of patients suffering from obesity are in middle age and these data confirm the textual references. It was found that the females registered in this study were 78 % and it confirmed that the *athisthaulya* occurs more in female than male. Generally female have more tendency to obese due to some feminine factors like puberty, menstrual disturbances, use of hormonal contraceptives, pregnancy, post operating condition, menopause. In addition, there is a general trend to more female hospital attendance in Ayurveda hospitals in the middle age group. Maximum patients 68 % were Buddhist; this may be only a reflection of predominance of Buddhist patients in hospitals located areas and hospital attendance. Among 60 patients, majority of the patients 78 % were married and showed relation ship between marriage and incidence of obesity. This may be due to the disease affects more in the middle age, generally persons remain married. In addition, married female found obese in comparison to unmarried, having hormonal imbalance occurring after marriage in pregnancy, use of hormonal contraceptives and postoperative conditions. Distribution of occupation in this study showed maximum patients 57 % were related to light physical work; energy expenditure is less so it may lead them to be obese. In this study showed maximum 58 % patients reported from good socio-economic group it showed that good and moderate socio-economic group persons prone to eat fast foods etc., leads to obesity.

Even though family history is one of the predisposition factors for obesity, in this study majority of the patients 77 % had negative family history. Distribution according to dietetic

habit showed majority 50 % patients of this study, were having high carbohydrate diet. Excessive intake of high calorie diet is well-known cause of obesity. Among 60 patients' majority 52 % patients were having *kapha-pita prakriti* and 32 % *kapha-vata prakriti*. It reveals most of the patients having *kapha* dominant *deha prakurthi*, tend to *athisthaulya* easily. This observation proves and validates the Ayurveda theory. Distribution according to causative factors contributing to *athisthaulya* showed majority 50 % of patients noted less physical exercise (*avyayama*) and over intake of food (*atibojana*), which reduce metabolism, aggravates *kapha* and *medodhathu* resulting *athisthaulya*. It proves that most of the causative factors are preventable. According to data of symptom wise distribution majority of the patients 45 % had excessive sweating (*swedadikyatha*). In this study majority of the patients i.e. 33.3 % had weight between 81.0 - 90.0 kg, majority of the patients i.e 57 % belong to 30 – 34.9 kg / m<sup>2</sup> (obese) BMI range and 45 % were having serum cholesterol in the range of 120.0 - 180.0 mg / dl.

After four weeks of treatment symptoms of the *athisthaulya* group 1 patients shows significant reduction ( $p \leq 0.05$ ) in shortness of breath (*kshudra swasa*), Thirsty (*atipipasa*), excessive hunger (*athiagni*), excessive sweating (*swedadikyatha*), pendulous breast (*chala sthana*), pendulous abdomen (*chala udara*), pendulous buttocks (*chala sphick*), excessive sleepiness (*nidradhikya*), poor physical capacity (*daurbalya*) and heaviness in the body (*angagaurava*) and were comparable to the group 2 (Table1).

**Table 1: Effect on symptoms present in group 1 and 2 patients.**

Effect on symptoms	Group 1 SMD (n= 30)			Group 2 GC (n=30)		
	BT Mean	AT Mean	P value	BT Mean	AT Mean	P Value
1 Shortness of breath ( <i>Kshudra swasa</i> )	1.33	0.93	0.008	0.97	0.33	0.001
2 Thirsty ( <i>Atipipasa</i> )	0.80	0.53	0.018	0.80	0.23	0.007
3 Excessive hunger ( <i>Athiagni</i> )	1.03	0.77	0.009	1.13	0.37	0.001
4 Excessive sweating ( <i>Swedadikyatha</i> )	0.83	0.33	0.001	1.37	0.57	0.000
5 Bad smell of the body ( <i>Daurgandhya</i> )	0.30	0.23	0.325	0.20	0.07	0.161
6 Pendulous breast ( <i>Chala sthana</i> )	1.07	0.83	0.032	1.33	0.47	0.000
7 Pendulous abdomen ( <i>Chala udara</i> )	1.30	1.03	0.030	1.37	0.43	0.000
8 Pendulous buttocks ( <i>Chala sphick</i> )	0.87	0.70	0.027	1.73	0.60	0.000



9	Excessive sleepiness ( <i>Nidradhikya</i> )	0.70	0.57	0.043	1.00	0.37	0.001
10	Poor physical capacity ( <i>Daurbalya</i> )	0.53	0.30	0.006	0.57	0.23	0.023
11	Heaviness in the body ( <i>Angagaurava</i> )	1.03	0.50	0.000	0.53	0.17	0.046

Values are significant at  $p \leq 0.05$

When comparing with the standard drug, GC (group 1) with SMD (group 2), the body weight, BMI and the anthropometric measurements of both groups also comparably decreased significantly ( $p = 0.00$ ) after four months of treatment (Table 2). These results revealed that the test drug SMD has weight reducing and lipid lowering properties. Therefore, SMD can be use as effective medicine for the *athisthaulya*.

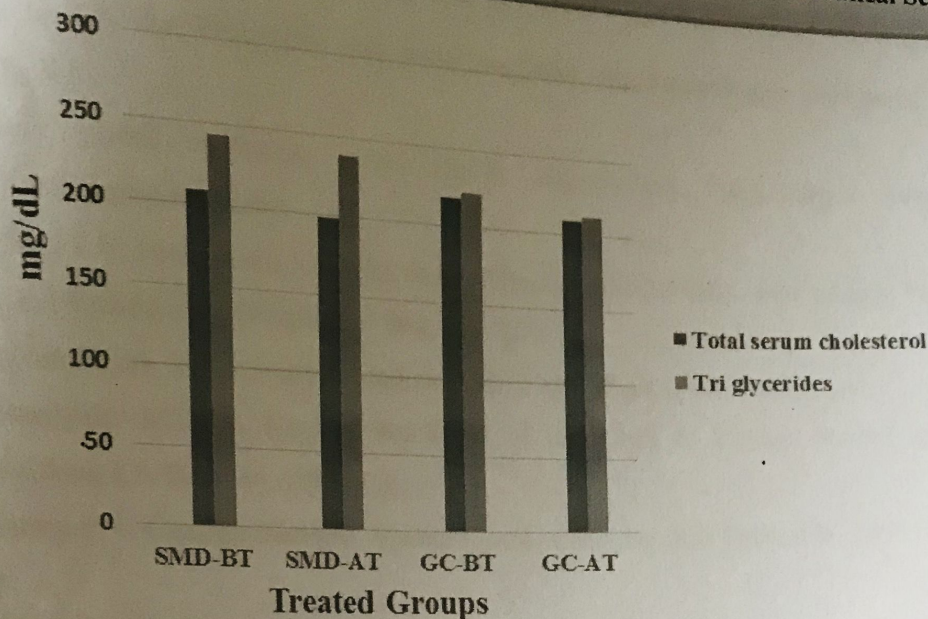
*Sihin Midi* has *katu*, (pungent), *thiktha* (bitter), *kashaya* (astringent) tastes, *sukshma* (finess) and *ruksha guna* (rough quality), *ushna virya* (hot in potency) and *katu vipaka* (pungent after effect). Therefore, it is apparent that all *rasa, guna, virya* and *vipaka* of SMD led to reduce *kapha* and *meda* and result of that heesumay reducing and then reducing effect on *athisthaulya*.

**Table 2: Effect on the body weight, BMI and the anthropometric measurements of both groups.**

Effect on anthropometric measurements	Group 1 SMD (n= 30) Mean Score		Group 2 GC (n=30) Mean Score	
	BT	AT	BT	AT
Chest	101.2+ 5.22	98.3+ 3.12	104.1+ 4.32	100.3+ 4.13
waist	94.85+ 4.23	93.15+ 5.14	95.45+ 4.23	93.38+ 3.44
Hip	106.65+5.31	106.41+ 5.22	109 .75+ 5.24	107.27+ 5.23
Biceps	1.63+ 0.24	1.53+ 0.24	1.52+ 0.24	1.42+ 0.24
Sub scapular	1.73+ 0.24	1.52 + 0.24	1.58 +0.34	1.45 + 0.24
Body weight (kg)	86.65+ 0.24	84.10 + 0.24	80.17	77.68 + 0.24
BMI	36.54 + 0.24	35.46+ 0.24	32.11+ 7.28	31.12 + 0.24

Values are significant at  $p \leq 0.05$

The mean total serum cholesterol and mean serum triglyceride of SMD group was significantly ( $p = 0.00$ ) reduced to 9.8 mg / dl and 4.15 mg/dl respectively as compared with the GC group which received 250.0 mg of standared drug, Guggulu.mean score of serum total cholesterol was reduced (Fig.1.).



**Fig. 1: Effect of SMD and GC on total serum cholesterol and serum triglyceraldehyde levels before Treatment (BT) and After Treatment (AT).**

The Results are Compared to Control. Values are significant at  $p \leq 0.05$

### CONCLUSION

The observation of the study was validated and consolidated the etiology of *athisthaulya* mentioned in Ayurveda. This present study had proven that, decoction of *Sihin midi* (SMD) could be effective for the treatment of obesity and hyperlipidemia. These observations provide some valuable scientific support for the therapeutic application of the decoction of *Sihin midi* (SMD) in the traditional medical system in Sri Lanka.

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### Conflict of interest

The authors declare that there is no conflict of interest.

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