A Clinical Study on the Effect and Efficacy of Traditional Formulation Derived by Ola Leaves Manuscript In The Management of Overweight And Obesity

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Abstract- Overweight and obesity are defined as abnormal or excessive fat accumulation that presents a risk to health. Once considered a high-income country problem, overweight and obesity are now on the rise in low and middle-income countries, particularly in urban settings. The treatment modalities have been unsuccessful even in this modern technologically-advanced era. Herbal drugs have been used in the treatment of *Staulya* since ancient times. Thus in this research, it was intended to investigate the effect of *Virechana* formulae in *ola* leave manuscript for overweight and obesity control in Sri Lankan context. Group A was treated with herbal formula for 4 weeks duration and Group B was firstly treated with *Virechana* procedure and then prescribed herbal formula for two weeks duration. When analysing the results of Group B, BMI shows a P value of 0.000 which were highly significance. The mentioned traditional herbal formula is effective for the management of overweight and obesity related parameters. But it was more effective with the combination of *Virechana* procedure than individual. The overall results of present study evidence that the short term administration of new herbal formulation has shown significant effect in decreasing the overweight and Obesity. So the new herbal formulation is an effective remedy for the management of Overweight and Obesity.

Index Terms- Overweight, Obesity, Staulya, Virechana

I. INTRODUCTION

Overweight and obesity are defined as abnormal or excessive fat accumulation that presents a risk to health (Finucane, *et al*., 2011). A crude population measure of overweight and obesity is the body mass index (BMI), a person's weight in kilograms divided by the square of his or her height in meters. A person with a BMI of 30 or more is generally considered obese. A person with a BMI equal to or more than 25 is considered overweight (WHO, 2015).

BMI is a simple index of weight-for-height that is commonly used to classify overweight and obesity in adults. It is defined as a person's weight in kilograms divided by the square of his height in meters (kg/m^2). The World Health Organization (WHO) definition is BMI greater than or equal to 25 is overweight; a BMI greater than or equal to 30 is obesity; 30.0 - 35.0 - class I obesity; 35.0 - 40.0 - class II obesity; 40.0 - class III obesity and BMI $\geq$ 35 or 40 kg/m^2 is severe obesity (Debasis and Harry, 2008)[i]. BMI provides the most useful population level measure of overweight and obesity as it is the same for both sexes and for all ages of adults. However, it should be considered a rough guide because it may not correspond to the same degree of fatness in different individuals (Molarius, *et al*, 2005). The worldwide prevalence of overweight and obesity more than doubled between 1980 and 2014.

Once considered a high-income country problem, overweight and obesity are now on the rise in low and middle-income countries, particularly in urban settings (Am and Clin, 1998)[ii]. In developing countries with emerging economies (classified by the World Bank as lower and middle-income countries) the rate of increase of childhood overweight and obesity has been more than 30% higher than that of developed countries.

According to the proposed World Health Organization cut-off values for Asians, the percentage of Sri Lankan adults in the overweight, obese and centrally obese categories were 25.2%, 9.2% and 26.2%, respectively (WHO, 2015). Based on the cut-offs for Caucasians, these were 16.8%, 3.7% and 10.8%. Our findings were compatible with prevalence of obesity in regional countries. In addition, female sex, urban living, higher education, higher income and being in the middle age were shown to be associated with overweight and obesity in Sri Lankans (WHO, 2015).

Overweight and obesity are linked to more deaths worldwide than underweight. Those are major risk factors for a number of chronic diseases, including diabetes, cardiovascular diseases and cancer. Once considered a problem only in high income countries, overweight and obesity are now dramatically on the rise in low- and middle-income countries, particularly in urban settings (Flegal, *et al*., 2010).

The fundamental cause of obesity and overweight is an energy imbalance between calories consumed and calories expended (National Institutes of Health, 1998). Globally, there has been, an increased intake of energy-dense foods that are high in fat,while an increase in physical inactivity due to the increasingly sedentary nature of many forms of work, changing modes of

transportation, and increasing urbanization (Flegal, *et al*, 2010). Raised BMI is a major risk factor for the non- communicable diseases such as cardiovascular diseases (mainly heart disease and stroke), diabetes, musculoskeletal disorders (especially osteoarthritis - a highly disabling degenerative disease of the joints) which were the leading causes of death in 2012 in the world (Zhang and Wang, 2012).

The *Ayurveda* texts, *'Charakacharya'* has described eight undesirable constitutions of the body and obesity is one of them which is described as *'Atisthulya'*. In an obese individual, *Medas* (Fat) is excessively nourished whereas the remaining *Dhatus* get underfed. When *Kapha* grows in an irregular fashion, fat metabolism gets affected and a person becomes obese.

The treatment modalities for overweight and obesity have been unsuccessful even in this modern technologically-advanced era. Due to the high cost of modern medical treatments and the rising number of patients with overweight and obesity directs the attention of the scientific community, doctors and patients, towards Chinese herbal medicine, Ayurveda medicine, and other popular alternative medical therapies (Guruprasad, *et al*., 2015).
Herbal drugs have been used in the treatment of overweight and obesity (*Stulya*) since ancient times. Natives in different continents had used herbs in their medicinal practices, while some cultures developed their own herbal medical systems, such as Ayurveda, Herbs are becoming more main stream as advances in scientific research show the importance of herbal medicinal practices in the diagnosis, treatment and prevention of disease.The presented study provides a general understanding of the actions of herbal formula and hence a background for understanding questions of safety and side-effects, especially regarding to their presumed beneficial effect (Hasani,*et al*., 2009). Some *Panchakarma* therapy like *Virechana* helped to manege diseases like *Sthaulya* and has hyperlipidemic activity too (Dissanayake and Tiwari, 2008).

Although much attention has been given to *Virechana* treatment formulae in *Ayurdeda* texts for controlling obesity, no much studies have been conducted so far on *Virechana* formulae on traditional obesity treatment in Sri Lanka. Thus in this research, it was intended to investigate the effect of Virechana formulae in *ola* leave manuscript for overweight and obesity control in Sri Lankan context.

II. MATERIALS AND METHODS

General objective

Evaluate the effect and efficacy of selected *Virechana* formulation by *ola* leaves manuscript in the management of overweight and obesity.

Selection of the Patients

Volunteer patients between 18 and 60 years of age who were overweight and obese were selected from Obesity clinic, Gampaha Wickramarachchi Teaching Hospital, Yakkala and Obesity clinic, Hela Veda Piyasa, Belummahara. They were included for study if they were classified as overweight if their body mass index (BMI; weight in kilograms divided by height in square meters) was ≥25 kg/m^2, or obese if their BMI was ≥30 kg/m^2. This determination was based on heights and weights recorded in the medical records.

Design of the research

Randomized comparative clinical trial , to determine the effect of *Virechana* formula in the management of Overweight and Obesity. Group A was given *Traditional Herbal Choorna* 15g twice a day for 1 month. Group B was treated with *virechana karma* and after *Traditional Herbal Choorna* 15g twice a day for 2 weeks. On the day of *Virechana* 60g of same herbal formula put on to the 960ml of water and boil until reduce to 240ml. The 240 ml of decoction was given to the empty stomach. After 1 month BMI observed.

Assessment Criteria

BMI (Body Mass Index) (Singh, 1993)
Overweight – 25 – 29.9 Kg/m2
Obesity (class-I) 30 – 34.9 Kg/m2
Obesity (class-II) 35 – 39.9 Kg/m2

Data Analysis

Results were expressed as mean ± SD significant of difference was value vetoed using the SPSS statistical program package. (SPSS 16 Inc. USA) and defined at 0.05.levels of confidence.

III. RESULTS AND DISCUSSION

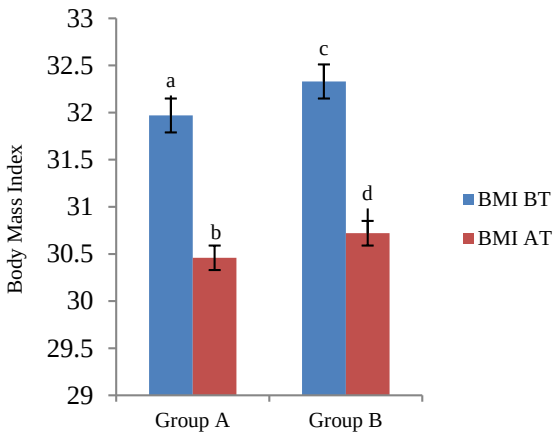
Table 1 Effect of the Therapy of two Groups in BMI (Before and after treatments)

Groups N=25	BMI (Kg/m2)
Group A BT	31.97±0.35^a
Group A AT	30.46±0.42^b
Group B BT	32.33±0.56^c
Group B AT	30.72±0.58^d

[In a column, data are presented as Mean± SEM of 25 patients per each group. In each column, data indicated by different superscript letters are significantly different from each other.]

Statistical analysis revealed that there was 1.50 improvement in mean value of BMI score after giving Herbal *choorna* in Group A and this change is statistically highly significant according to the 2-tailed test (P=<0.000).There was 1.61 improvement in mean value of BMI score after giving *Virechana* and Herbal *choorna* in Group B and this change is statistically highly significant (P=<0.000). And also there were strong positive correlation between before treatment and after treatment results in both groups and correlation of the Group B is more significant than Group A.

Figure 1 Effect of the therapy of two groups in BMI (Before and after treatments)



The new herbal formula consists of *Nigella sativa* (*Kaluduru*), *Saussurea lappa (Suvanda Kottan)*, *Zingiber officinale* (*Inguru*), *Allium sativum* (*Sudu lunu*), *Cassia fistula* (*Ehela*) *and Cassia senna* (*Senehe kola*). When analyzing the new herbal formula, mainly it has *Katu*, *Tikta*, *Madura rasa*, *Laghu*, *Ruksha*, *Ushna*, *Teekshna* and *Sara guna*, *Ushna veerya*, *Katu vipaka* and *Vata-Kapha shamaka*, *Virechaka karma.* So literature findings revealed that the new herbal formula has *Kapha* reducing and *Virechana* activity. Dissanayake and Tiwari explained that *Sthaulya* can manage successfully by using some *Samshodana* and *Samshamana* therapy and *Panchakarma* therapy like *Virechana* and has hyperlipidemic activity too. And BMI also showed highly significant value in before and after treatments in both Groups but higher mean difference in Group B. This results shows that the *virecharana* is more helpful to maintain the balance of body tissues than oral administration of drugs. It means that *samshodana* with *samshamana karma* is more effective than individual usage of *samshamana cikitsa.*

IV. CONCLUTION

According to the above sited facts the mentioned traditional herbal formula is effective for the management of overweight and obesity related parameters. But it was more effective with the combination of *Virechana* procedure than individual. The overall results of present study concluded that the short term administration of new herbal formulation has shown significant effect in decreasing the overweight and Obesity. So the new herbal formulation is an effective remedy for the management of Overweight and Obesity.

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