



EXPLORATION OF NISHA-AMALAKI YOGA IN THE MANAGEMENT OF OBESITY

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ABSTRACT

Sthaulya (Obesity) is considered the world's oldest metabolic disorder. It is not a single disease entity but a syndrome with many causes including combination of genetic, nutritional and sociological factors. WHO considers obesity as "Insidious, creeping pandemic which is now engulfing the entire world". Obesity develops as a result of a complex interaction between a person's genes and the environment characterized by long term energy imbalance due to excessive caloric consumption, insufficient energy output (sedentary lifestyle, low resting metabolic rate) or both. Obesity increases the likelihood of various diseases, particularly heart disease, type 2 diabetes, breathing difficulties during sleep, certain types of cancer, and osteoarthritis. Nisha Amalaki Churna was given to 50 obese patients 3 gms twice a day for 12 weeks. As mentioned in samhitas "Meheshu Dhatri Nisha" and all prodromal symptoms of Prameha are seen in medadhathujanita vikaras hence this kalpa was used in obesity. After completion of therapy, 1.130 kg reduction of body weight were noted. The symptomatic result was found to be statistically highly significant. No adverse effects were observed in any of the treated patients.

KEYWORDS: Obesity, Nisha-Amalaki yoga, Haldi, Amla, Sthaulya, Medovridhi, Metabolic disorder.

1. INTRODUCTION

Obesity (*Medovridhi*) is the most common metabolic disorder in affluent societies caused by excessive eating, lack of exercise and is a direct result of the modernization combined with lifestyle changes. As mentioned in *Astanghrudaya Uttartantrachp* 40/48 *Mehashu Dhatri nisha* in Prameha. All clinical signs and symptoms of *medovaha strotas dusti lakshanas* are seen in *purvarupa of prameha*. Hence *Dhatri nisharasyana* drug is selected to correct the metabolism of *medovahastrotas dusti* in *medoroga*. In *Rasayana adhyaya*, Charaka stated that *rasayanachikitsa* should be done in *Oja-kshaya* and *Dhatushithilata* stage for qualitative production of *dhatu*. *Dhatri nisha* is currently prescribed for T2DM. In this study, we explore whether it can also be used for reducing obesity in humans, as it is often a precursor to T2DM. This may help prevent the progression from obesity to T2DM or other serious obesity-related diseases]. Further exploratory clinical study was carried out with *Amalaki*, and *Haridra* in obesity by me.

2. AIMS AND OBJECTIVES

- A) Aims:** To explore the possible role of nishaamalaki yoga in the management of Obesity.
- B) Objectives:**
1. To explore the effect of *Nishaamalaki* on B.M.I.

2. To explore the effect of *Nishaamalaki* on Weight.
3. To explore the role of *Nishaamalaki* on serum Lipids.
4. To explore the effect of *Nishaamalaki* on Waist circumference
5. To explore the effect of *Nishaamalaki* on Ayurvedic parameters like Excessive hunger (*Kshudha*), Excessive thirst *Trushna*, Excessive sleep (*atinidra*)

MATERIALS AND METHODOLOGY

Sample size: For exploratory studies, statisticians recommend minimum 30 subjects. We sought to test *Nishamalaki* on 94 obese patients who presented themselves at our clinic and satisfied certain inclusion-exclusion criteria. 50 of them completed the full term of the study. All analysis was therefore done on these 50 individuals. According to biostatisticians, this number is adequate for applying statistical methods and drawing reasonably powerful inference.

1. Test group: *NishaAmalaki Churna* was given to 50 obese patients twice a day for 12 weeks.
2. Written, informed consent of the patient was taken prior to the clinical trial.
3. Patients were given *NishaAmalaki Churna* 6gm/day in two divided doses
4. Follow up was taken at the monthly intervals for 3 months

5. Biochemical investigation Lipid profile was done on Day 1 and after 90days.

Inclusion Criteria

1. Obesity diagnosed as B.M.I. more than 25.0
2. Age group between 20-60 Yrs. irrespective of sex, religion, socio- economic status, marital status was selected.

Exclusion Criteria

1. Pregnant women, lactating mothers.
2. Acute life threatening conditions.
3. Patients with long term Steroid treatment.
4. Patients with severe Hypertension.
5. Patients with evidence of Renal, Hepatic and Cardiac involvement.
6. Patients suffering from cardiovascular disease, Cushing's syndrome, endogenous obesity and from other such disease in which the patients cannot do his routine physical activity can be excluded.
7. Morbid obesity (*Ati-Sthaulya*) patients having B.M.I. >45 will be excluded
8. Females using oral contraceptives.
9. Obesity associated cancer.
10. Insulin dependent subjects
11. Patients on antipsychotics, anti convulsants, antidepressants drugs.
12. Congenital obese.
13. Patients suffering from endocrine disorders like hypothyroidism.
14. Patient dependent on any other remedial treatment.

Assessment Criteria

The effect of the study formulation was assessed on the basis of Body weight, BMI, anthropometry and biochemical investigations was done before starting the treatment and after completion of treatment and was subjected to statistical evaluations.

Additionally, presence/absence of Ayurvedic signs and symptoms of obesity was documented pre and post therapy.

Withdrawal Criteria

1. If patients develops any adverse effect.
2. Patient's refuses to continue treatment.

Statistical methods

All statistical tests were conducted using the well-validated online calculators at VassarStats.

Complete data was available for 50 individuals over 4 time points for following quantitative variables.

Body weight, BMI, waist circumference.

All data was tested for normal probability distribution. Only WHR, a ratio of 2 normal variable, was not consistent with normal distribution, and hence, the data was converted to ranks and analyzed using Friedman

test. All the other data was analysed using One-way ANOVA. Null hypothesis that the treatment showed no effect was tested against the alternative hypothesis that it showed some effect.

Complete data was available for 50 individuals over 4 time points for following qualitative variables.

Atinidra,

For each variable, the data was rank ordered as required by Friedman test, and the hypothesis of lack of effect of treatment was tested against the hypothesis that the treatment showed some effect.

Given $k=4$ correlated samples of n measures each, of the general form shown in the adjacent table, the Friedman test begins by rank-ordering the values across each of the rows, which is tantamount to ranking the measures within each of the n subjects or within each of the n randomized blocks, depending on the design. The resulting ranks are then summed down the columns. On the null hypothesis that there is no difference among the k sets of measures, the sum of each column of ranks should approximate $n(k+1)/2$. As a measure of the aggregate degree to which the observed column rank sums differ from this null-hypothesis value, the Friedman test calculates a version of the chi-square statistic, which is symbolized here as csq_r . [ref: VassarStats webpage]

For variables, Daurgandhya, complete data for 50 individuals at start of study (Day1) and end of study (Day 90) was available. Data was of binary type at each time point, and could be converted to a 2x2 contingency table for "Before" and "After" treatment. Such data was analyzed using McNemar test.

OBSERVATIONS AND RESULTS

The demographic data of 50 registered patients of obesity revealed that maximum 34% patients belonged to age group of 31-40 years followed by 30% of 41-50 years and females (80.30%). Sex-wise maximum patients were females (76%). Majority of patients were housewives (52%), followed by service class patients (28%) had history of sedentary type of work, *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 (70%).

Maximum patients in the exploratory trial were having positive family history of obesity (68%) while no significant family history of obesity was found in 32% patients.

For following variables, which have quantitative measurements, repeated measures one-way ANOVA was done : BMI, Body weight; circumferences of Abdomen, Midarm, Waist and Hip, WHR; Total cholesterol, TG, LDL, VLDL, HDL.

The results are summarized below.

BMI

Statistically significant difference is found in BMI in the 4-time point follow-up studies ($F=9.77$, $Df=3$, $p<0.0001$).

Tukey's post-hoc HSD test shows that the difference is between the pairs, Day 1 and Day 90, and Day 30 and Day 90 ($p<0.01$). Mean change in BMI between Day 1 and Day 90 is 0.187.

Category	Day 1	Day 90
overweight	18	25
Obese	32	25

Body Weight

Statistically significant difference is found in BW in the 4-time point follow-up studies ($F=5.67$, $Df=3$, $p=0.00106$).

Tukey's post-hoc HSD test shows that the difference is between the pairs, Day 1 and Day 90, and Day 30 and Day 90 measurements ($p<0.01$).

Mean change in body weight between Day 1 and Day 90 is 1.13 kg.

This matches the result for BMI, as expected, because height does not change over the course of the study.

Mid-arm circumference

Statistically significant difference is found in mid-arm circumference in the 4-time point follow-up studies ($F=7.42$, $Df=3$, $p=0.0001$).

Abdomen circumference

No difference is found between circumference of waist over the 4-point follow-up studies ($F=0.13$, $df=3$, $p=0.94$).

Waist circumference

Statistically significant difference is found in waist circumference in the 4-time point follow-up studies ($F=18.96$, $Df=3$, $p<0.0001$).

Tukey's post-hoc HSD test shows that the difference is between the pairs, Day 1 and Day 30 ($p<0.05$), Day 1 and Day 60 ($p<0.01$), Day 1 and Day 90 ($p<0.01$), Day 30 and Day 90 ($p<0.01$), and Day 60 and Day 90 measurements ($p<0.01$). This shows significant effect on waist circumference all through the treatment.

Mean change in waist circumference between Day 1 and Day 90 is 2.84 cm.

Hip circumference

Statistically significant difference is found in hip circumference in the 4-time point follow-up studies ($F=17.19$, $Df=3$, $p<0.0001$).

Tukey's post-hoc HSD test shows that the difference is between the pairs, Day 1 and Day 60, Day 1 and Day 90, and Day 30 and Day 90 measurements (all with $p<0.01$).

WHR (Waist to hip ratio.)

As WHR is a ratio and Shapiro-Wilks test did not show the data to be consistent with normal probability distribution, Friedman test was done on the ranked WHR data over the 4 time points.

Mean Ranks for Sample			
A	B	C	D
2.8	2.5	2.5	2.2

$CSQ_r = 6.2$

$df = 3$

$P = 0.1023$

If n is sufficiently large, the sampling distribution of csq_r is a close approximation of the sampling distribution of chi-square with $df=k-1$. With $k=4$ and $df=3$, "sufficiently large" begins at about $n=5$. If the size of your sample is smaller than 5, you should treat the calculated P-value as an imperfect approximation.

Statistically insignificant difference is found in WHR in the 4-time point follow-up studies ($F=3.43$, $Df=3$, $p=0.1023$).

Total Cholesterol

There is no effect of treatment on cholesterol by Anova test. ($F=0.41$, $df=3$, $p=0.525$).

Triglyceride

There is no effect of treatment on triglyceride by Anova test. ($F=0.79$, $df=3$, $p=0.378$).

LDL

There is no effect of treatment on LDL by Anova test. ($F=0.22$, $df=3$, $p=0.641$).

VLDL

There is no effect of treatment on VLDL by Anova test. ($N=96$, $F=0.5$, $df=3$, $p=0.483$).

HDL

There is no effect of treatment on HDL by Anova test. ($F=0.08$, $df=3$, $p=0.778$).

Overall conclusion for measured variates:

While the treatment has statistically significant effect on body size and weight, it does not affect cholesterol. Perhaps, continuing the treatment for longer time will show an effect on lipid profile.

Statistical Methods and analysis of clinical Ayurveda parameters

Where the data is qualitative or ranked, we have used Friedman test for these parameters.

Friedman Test for $k=4$ (time points), $n=50$ (individuals).

Excessive Hunger, Trushna, Atinidra

There is statistically significant difference between observations at the start of the study and at the end of the study for these variates : Excessive Hunger, *Trushna* and *Atinidra* at 0.01% level of significance.

There is statistically significant difference in Daurbalya between Day 1 and Day 90 ($p=0.000004$).

DISCUSSION

The data shows a statistically highly significant relief was found in *Atikshudha*, *Atipipasa*, *Atinidra*. Disease *Sthaulya* originates due to consumption of *Kapha* *Vridhikara Ahara* (diet), *Vihara* (regimen) and *Manasa* (psychological) *Nidana* (causes). These factors dearrange *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 disease *Sthaulya*. Combination of *Amla* (sour), *Tikta* (bitter), *Kashay* (astringent) and *Katu* (pungent) *Rasa*, *Laghu*, *Ruksha Guna* in *Dhatrinisha Yoga* having all the properties which can do the function of *Strotovibandhanashana* and against *Kapha*, *Kleda* and *Meda*. *Lekhaniya* (bio scraper), *Rasayana* (rejuvenation) properties, which normalize the state of *Agni*. Thus, regulated *Jatharagni*, *Medadhatvagni* checks the excessive growth and accumulation of fatty tissue. 2.

Nisha-Amalaki improves the function of *Bhutagni*. *Nisha-amalaki* improves the function of *Parthiva* and *Jala bhutagni*.

Drug like *amalaki*, possessing *Madhura Rasa* may help to soften and uncton the vessels hardened overtime by the deposited fat as in the case in Atherosclerosis.4 *Amalaki* is an antioxidant with free radical scavenging properties which may be due to the presence of high levels of super oxide dismutase.1 Antioxidant activity is reported of active tannoid principle of *Emblica officinalis* in IJ of experimental biology 1999 A studies conducted on mice showed that turmeric extract inhibited

membrane phospholipids per oxidation and increased liver lipid metabolism, which indicates turmeric extract has the ability to prevent the deposition of triacylglycerols in the liver.3.

Effect on biochemical parameters

During the study Biochemical Parameters before and after treatment were found different. Slight decrease in values of serum triglycerides mean from 143.29 to 129.26mg/dl which was not statistically significant after completion of the exploratory trial. Few cases of patients where triglyceride was 386mg/dl were reduced to 205mg/dl, 208mg/dl to 120mg/dl. Other Biochemical parameter like Serum Cholesterol, LDL, HDL, also showed Statistically insignificant changes.

CONCLUSION

- Results of this study are encouraging and trial can be conducted as concomitant therapy on large sample and for longer duration at least six months.
- *Nisha –amalaki* can be used in early stages of obesity to prevent complications of obesity.

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