

Clinical evaluation of trivrt yukta navaka guggulu in obesity

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ABSTRACT

Overweight and obesity is commonly assessed by using body mass index (BMI), BMI over 25 kg/m² is defined as overweight, and over 30 kg/m² as obese. Currently more than 1 billion adults are overweight - and at least 300 million of them are clinically obese globally and Obesity accounts for 2-6% of total health care costs in several developed countries (WHO). Ayurveda describes eight types of despicable designated as 'Ninditapurusha', atisthaulya (obesity) is one of them. Obesity poses major health risk factors for chronic diseases, including type 2 diabetes, cardiovascular diseases including hypertension, I.H.D and stroke, and certain forms of cancer. In the present study 67 patients of obesity were treated with trivrt yukta navaka guggulu. After course of therapy 3.96 ± 0.29 (mean difference ± SE) and 1.63 ± 0.12 reduction of body weight and body mass index was noted. The result was found statistically highly significant (p<0.001). No clinical adverse effect was observed in any of the patients.

Key words: Overweight, Obesity, Sthaulya, Trivrit yukta navaka guggulu

INTRODUCTION

Obesity is known as '*Medo Roga*' in Ayurveda¹ and is defined as the condition in which excessive amount of fat is accumulated in the body. When the *agni* (digestive fire) is being vitiated, the *ama* (toxic substances) is built up in the body, leading to obesity. Overweight and obesity is commonly assessed by using body mass index (BMI), BMI over 25 kg/m² is defined as overweight, and over 30 kg/m² as obese². These markers provide common benchmarks for assessment, but the risks of disease in all populations can increase progressively from lower BMI levels. Obesity and overweight pose a major risk for serious diet-related chronic diseases, including

type 2 diabetes, cardiovascular disease, hypertension and stroke, and certain forms of cancer. The health consequences range from increased risk of premature death, to serious chronic conditions that reduce the overall quality of life. Classical Ayurvedic texts describes 8 types of despicable designated as *ninditapurusha*, *atisthaulya* (obesity) is one of them. Corpulent people are a) short in longevity, b) slow movement, c) difficult to indulge sex, d) weak, e) emission of bad body odour, f) profuse perspiration, g) excessive hunger & h) excessive thirst³. Body is made up of structure of bones, muscles and fat filling the gaps. The fat storage in a healthy human is about 15% of the body weight. A large proportion of fat is stored subcutaneously all over the body but specially in the buttocks, abdomen, checks, chins etc.⁴

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Although a variety of medications are available to treat obesity like appetite suppressants, HMG- co reductase inhibitors, pancreatic lipase inhibitors, S-NRI etc. and bariatric surgery but have not been able to control the increasing number of obese in the society. More over modern drugs have limitations in their actions and are not free

from side effects. The physicians of Indian System of Medicine are treating this condition for thousands of years with the drugs having no remarkable side effects. Ayurveda is based on scientific principles of diagnosis and treatment (*nidana* and *chikitsa*). 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 & mineral products. Many cost effective Indian medicinal plants have come after scientific scrutiny since middle of 19th century, although in sporadic fashion having no remarkable side effects ⁵.

The present study deals with the herbal compound containing classical preparation *navaka guggulu*⁶ with *trivrit* (*Operculina turpethum* Linn.) indicated for obesity.

AIMS & OBJECTIVES

To explore the aetiopathogenesis of *sthaulya* according to Ayurveda & modern medical science and to evaluate the therapeutic efficacy and adverse effects of *trivrit yukta navaka guggulu*.

MATERIALS AND METHOD

Total 67 patients of *sthaulya* were registered from OPD & IPD of I.P.G.T& R.A, hospital, Jamnagar fulfilling the clinical diagnostic criteria of the disease *sthaulya* based on Ayurvedic & modern parameters. Out of 67 registered patients, 53 patients had completed the treatment and remaining 14 patients had dropped out at different intervals. Reason behind the dropped out was that 03 patients were migrated to another place for job, 05 patients had poor compliance and were unable for regular check up, 02 female patients was conceived (pregnancy), and 3 patients had lack of faith in Ayurvedic medicine and one patient had an accident and could not attend hospital for routine checkup.

INCLUSION CRITERIA

The patients of *sthaulya* (obesity) were selected after taking short history from the O.P.D & I.P.D of I.P.G.T&R.A, hospital. The patients between the age group 20 years to 60 years of age were selected for present study. The patients selected for clinical trial according to sign and symptoms of *sthaulyata* following Ayurveda, and modern parameter. BMI -18.5-24.9 is normal; 25-29.9 over weight, 30-34.9 obesity class-I, 35-39.9 class II. Thus cases between BMI > 25Kg. /m²and < 40 Kg. /m² were included.

SUBJECTIVE CRITERIA

A detailed proforma incorporating all clinical aspects mentioned for *sthaulya*/obesity was prepared. Detailed medical history and thorough clinical/physical examinations were done. The signs and symptoms of *sthaulya* mentioned in Ayurveda were assigned a suitable scoring pattern to assess the condition of the patients before & after the completion of therapy.

OBJECTIVE CRITERIA

Assessment of patients by B.M.I (body mass index)= weight(in kg)/height(metre)², body circumference (cm), skin fold thickness (cm), body fat%, BMR(basal metabolic rate) and laboratory investigations carried out before and after treatment include : a) routine hematological investigations including Hb%, TC, DC, ESR; b) biochemical examinations like blood sugar (fasting and post prandial), lipid profile (serum cholesterol, serum HDL, serum LDL, triglyceride), blood urea and serum creatinine, serum T₃, T₄, TSH (limited and selected cases to rule out thyroid function)

EXCLUSION CRITERIA

Patients below the age of 20 years and above the age of 60 years were excluded. Patients

with endocrine disorders like diabetes mellitus, hypothyroidism, cushing's syndrome and obesity with cardiac problems like hypertension, ischaemic heart disease, cardiac failure were excluded. Obesity with pregnancy and with other significant associated illness, patients taking corticosteroids, oral contraceptive pills and B.M.I-

40kg/m² and above i.e. class -III extremely high obesity and severe complicated cases were 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.

Table 1: Showing ingredients of trial drug

Sl. no.	Name of Drug	Latin Name	Part used
1	Shunthi	<i>Gingiber officinale</i>	Rhizome
2	Maricha	<i>Piper nigrum</i>	Fruit
3	Pippali	<i>Piper longum</i>	Fruit
4	Haritaki	<i>Terminalia chebula</i>	Fruit
5	Vibhitaki	<i>Terminalia belerica</i>	Fruit
6	Amalaki	<i>Embelia officinalis</i>	Fruit
7	Chitrak(Bark)	<i>Plumbago zeylanica</i>	Root
8	Nagarmotha	<i>Cyperus rotundus</i>	Root
9	Vayavidanga	<i>Embelia ribes</i>	Fruit
10	Suddha Guggulu	<i>Commiphora mukul</i>	Resin
11	Trivrita	<i>Operculina turpethum</i>	Root

The *navaka guggulu* was prepared in the pharmacy of G.A.U, Jamnagar as per reference from *Bhaisajya Ratnavali* (39/43) and finally mixed with powder of *trivrit* (1part) and tablet were prepared each of 500mg

whether the improvement provided by the therapy is sustained or otherwise.

METHOD OF PREPARATION

All the components of the trial drug were procured from the market by the pharmacy department of the university and duly identified. The ingredients were washed in clean water and dried under sunlight. Then each of the ingredients was finally powdered and mixed in the equal ratio, stirred well and tablet prepared each of 500 mg size then it was packed in polythene pouch each containing 56 tablets, the requirement of 2 week for each patients.

Dose: Two tablets twice daily (each of 500mg) before meal.

Duration: 10 weeks

Anupana: Lukewarm water.

Follow up

After completion of the treatment the patients have been examined for follow up for one month at the interval of 15 days to record

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 (SE), standard error (SE). Paired 't' test was carried out at $p < 0.05$, < 0.01 and < 0.001 . The obtained results were interpreted as: $p > 0.05$ consider as insignificant, < 0.01 to < 0.05 consider as significant and < 0.001 is highly significant and the p values are adapted from java script.⁷

OBSERVATIONS AND RESULT

The demographic data of 67 registered patients of obesity revealed that maximum patients (41.79%) had *Kapha-pittaja deha prakriti* followed by 31.35% and 26.86% had *kapha-vataja* and *vata pittaja deha prakriti* respectively. Maximum (41.78%) patients belonged to age group of 20-30 years followed by 38.80% of 31-40 years and were females (89.55%). Religion wise maximum patients were Hindus (71.64%). Majority of patients

Table 2: Salient features and their scoring pattern of *sthaulya*

S. No	Salient features & their scoring pattern	Grading score
1	<i>Bharvridhi</i> (rise of body weight) BMI - <27 kg/ m ² BMI - 27-29.9 kg/ m ² BMI - 30-32.9 kg/ m ² BMI - 33-35.9 kg/ m ² BMI - >36 kg/ m ²	0 1 2 3 4
2	<i>Angachalatwa</i> (pendulous movement of body parts) Absence of angachalatwa Little visible movement after fast movement Little visible movement after moderate movement Movement after mild movement Movement even after change of posture	0 1 2 3 4
3	<i>Angagauravata</i> (heaviness of body) Absence of gauravata Occasional heaviness Persistent heaviness relieved after rest Persistent heaviness not relieved after rest ,can do normal daily work Persistent heaviness can't do normal daily work.	0 1 2 3 4
4	<i>Swedadhikya</i> (excessive perspiration) Sweating after heavy work Sweating after little work Profuse Sweating after heavy work Profuse Sweating after minimum work Sweating even in resting condition	0 1 2 3 4
5	<i>Atipipasa</i> (excessive thirst) Normal thirst Up to 1 l excess intake of water 1 to 2 l excess intake of water 2 to 3 l excess intake of water More than 3 l excess intake of water	0 1 2 3 4
6	<i>Gatra daurgandha</i> (bad body odor) Absence of bad smell. Occasionally bad smell to close areas difficult to suppress with deodorants. Persistent bad smell felt from long distance & not suppress with deodorants. Persistent bad smell felt from long distance, even intolerance to the patient himself.	0 1 2 3

7	<p><i>Ati kshudha</i> (excessive hunger)</p> <p>Unwilling for food but could take the meal.</p> <p>Willing towards only most liking food & not others.</p> <p>Willing towards only one among katu/amla/lavana/madhura food stuffs.</p> <p>Willing towards some specific ahara /rasa/ vishesa</p> <p>Equal willing towards all the bhojjya padartha.</p>	<p>0</p> <p>1</p> <p>2</p> <p>3</p> <p>4</p>
8	<p><i>Kshudra shroas</i> (Dyspnoea on exertion)</p> <p>Dyspnoea after heavy work but relieved soon & up to tolerance.</p> <p>Dyspnoea after moderate work but relieved late & up to tolerance</p> <p>Dyspnoea after little work but relieved late & up to tolerance</p> <p>Dyspnoea after little work but relieved soon & beyond tolerance.</p> <p>Dyspnoea in resting condition.</p>	<p>0</p> <p>1</p> <p>2</p> <p>3</p> <p>4</p>
9	<p><i>Utsaha hani</i> (lack of energy)</p> <p>No alasya</p> <p>Doing work satisfactorily with late initiation.</p> <p>Doing work unsatisfactorily with lot of mental pressure & late in time.</p> <p>Not starting any work in his own responsibility, doing little work very slowly</p> <p>Dyspnoea in resting condition.</p>	<p>0</p> <p>1</p> <p>2</p> <p>3</p> <p>4</p>
10	<p><i>Maithuna hani</i> (loss of libido)</p> <p>Unimpaired libido & sexual performance.</p> <p>Decrease libido but can perform sexual act.</p> <p>Decrease libido but can perform sexual act with difficulty.</p> <p>Loss of libido and can't perform sexual act.</p>	<p>0</p> <p>1</p> <p>2</p> <p>3</p>
12	<p><i>Snigdhangata</i>(unctuousness of body)</p> <p>Normal snigdghata</p> <p>Oily lusture of body in summer season</p> <p>Oily lusture of body in dry season</p> <p>Excessive Oily lusture of body in dry season can be removed with difficulty.</p> <p>Persistent and profuse slickness all over body.</p>	<p>0</p> <p>1</p> <p>2</p> <p>3</p> <p>4</p>
13	<p><i>Daurbalya</i> (weakness)</p> <p>Can do routine exercise</p> <p>Can do moderate exercise without difficulty</p> <p>Can do only mild exercise</p> <p>Can do even mild exercise with very difficulty</p> <p>Can't do even mild exercise</p>	<p>0</p> <p>1</p> <p>2</p> <p>3</p> <p>4</p>

Table 3: Main subjective features of various prakriti⁸

Features	<i>Vata prakriti</i>	<i>Pitta prakriti</i>	<i>Kapha prakriti</i>
Appetite	Irregular	Sharp	Low
Bowel habit	Constipated & irregular	Unformed faces	Regular & well formed faces
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 4: Main objective features of various prakriti:⁽⁸⁾

Features	<i>Vata prakriti</i>	<i>Pitta prakriti</i>	<i>Kapha prakriti</i>
Body frame	Long or short but lean	Medium size	Large, plump, fleshy and fatty
Skin	Blackish, rough, cracking	Fair ,reddish with moles, freckles	Fair & 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 & moist
Tongue	Darkish	Coppery	Clean
Activity	Quick, light and active & frequently moves body parts	Moderately active body parts	Slow
Sleep	Scanty & interrupted	Moderate & sound	Deep and excessive

were housewives (71.64%), maximum patients were from urban area (91.04%) and from middle income group 50.74%. Maximum patients (44.77%) had history of sedentary type of work, indulge day sleep (80.59%) and vegetarian diet (73.13%) and had consumed *guru* (heavy), *madhur* (sweet) properties in their daily diet (53.73 %).

DISCUSSION

The data shows that statistically highly significant results was found in *Bharvridhi*, *angachalatwa*, *angagauravata*, *swedadhikya*, *atipipasa*, *kshudra shvas*, *atinidra*, *snigdhangata*, *daurbalya* ($p < 0.001$). While improvement in *utsaha hani* and *maithuna hani* was statistically insignificant ($p > 0.05$) and in *gatradaurgandha* and *atikshudha* relief was statistically significant ($p < 0.05$). The disease *sthaulya* originates due to consumption of *kapha*

Table 5: Response of treatment on subjective criteria

Clinical features	n	Meanscore		% of relief	SD	SE	t	p
		BT	AT					
<i>Bhar vridhhi</i>	53	2.547	2.094	17.777	0.502	0.069	6.560	<0.001
<i>Angachalatva</i>	12	1.75	1.166	33.333	0.514	0.148	3.924	<0.001
<i>Angagauravata</i>	35	1.828	0.028	98.437	0.405	0.068	26.239	<0.001
<i>Swedadhikya</i>	41	1.365	0.268	80.357	0.700	0.109	10.037	<0.001
<i>Ati pipasa</i>	31	1.806	0.451	75.00	0.709	0.127	10.633	<0.001
<i>Gatradaurgandhya</i>	13	1.307	0.769	41.176	0.660	0.183	2.940	<0.05
<i>Atikshudha</i>	40	3.00	1.225	59.166	0.946	0.149	11.854	<0.05
<i>Kshudrashwasa</i>	40	1.925	0.925	51.948	0.392	0.062	16.124	<0.001
<i>Utsahahani</i>	3	1.333	0.666	50.00	0.577	0.333	2.00	>0.05
<i>Maitihunaahani</i>	3	1.333	1.00	25.00	0.577	0.333	1.00	>0.05
<i>Atinidra</i>	24	2.166	0.416	80.769	1.073	0.219	7.987	<0.001
<i>Snigdhangata</i>	13	1.615	0.230	85.758	0.506	0.140	9.859	<0.001
<i>Daurbahya</i>	29	1.724	0.206	88.051	0.68	0.12	11.68	<0.001

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

Table 6: Response of treatment on weight & BMI

Parameters	n	Mean weight and BMI		% of relief	SD	SE	t	p
		BT	AT					
Weight (kg.)	53	82.03	78.07	4.82	2.15	0.29	13.41	<0.001
BMI (kg/m ²)	53	33.37	31.74	4.88	0.90	0.12	13.12	<0.001

Table 7: Response of treatment on organ measurement

Name of organ	n	Mean measurement(cm)		% of relief	SD	SE	t	p
		BT	AT					
Chest	53	103.17	100.94	2.16	2.06	0.28	7.86	<0.001
Abdomen	53	99.75	96.27	3.48	2.64	0.36	9.56	<0.001
Buttocks	53	115.36	112.91	2.12	2.84	0.39	6.27	<0.001
Thigh	53	56.20	54.66	2.75	1.15	0.15	9.73	<0.001
Shank	53	38.24	37.40	2.19	0.90	0.12	6.73	<0.001
Arm	53	33.27	31.30	5.92	0.88	0.12	16.22	<0.001

Table 8: Response of treatment on skin folds thickness

Name of fold	n	Mean measurement(cm)		% of relief	SD	SE	t	p
		BT	AT					
Biceps	53	2.51	2.27	9.46	0.19	0.02	8.99	<0.001
Triceps	53	3.00	2.73	8.79	0.19	0.02	9.75	<0.001
Scapular	53	3.19	2.96	7.13	0.19	0.02	8.33	<0.001
Abdomen	53	3.20	2.85	10.89	0.24	0.03	10.35	<0.001
Thigh	53	3.156	2.9	8.12	0.20	0.02	9.31	<0.001

Table 9: Effect on biochemical parameters

Name of parameter	n	Mean values		% of relief	SD	SE	t	p
		BT	AT					
ESR (mm/hr.)	53	29.20	23.39	19.89	17.39	2.28	2.43	>0.05
FBS(mg/dl)	53	94.43	93.32	1.17	12.85	1.76	0.63	>0.05
PPBS(mg/dl)	40	107.10	106.32	0.72	15.73	2.48	0.31	>0.05
Serum Cholesterol(mg/dl)	53	174.18	175.69	-0.86	26.98	3.70	0.40	>0.05
Serum HDL(mg/dl)	53	45.86	47.98	4.61	14.51	1.99	1.06	>0.05
Serum LDL(mg/dl)	53	105.75	101.86	3.68	26.46	3.63	1.07	>0.05
Serum Triglyceride(mg/dl)	53	111.92	128.69	-14.98	46.37	6.37	-2.63	>0.05

vriddhikara ahara (diet), *vihara* (regimen) and *manasa* (psychological) *nidana* (aetiology). These factors derange *jatharagni* (abdominal fire/ digestive juices and enzymes) 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 *medodhatu*, causing the disease *Sthaulya*. Drugs of *Trivrit Yukta Navaka Guggulu* contains *amalaki*, *haritaki*, *vibhitaki*, *sunthi*, *maricha*, *pippali*, *chitrak*, *musta*, *vidanga*, *guggulu* and *trivrit*. *Amalaki* (*Embelia officinalis*) reduces aortic and hepatic cholesterol⁹ and triglycerides¹⁰. *Terminalia chebula* reduces cholesterol and cholesterol content of the liver and aorta.¹¹ Previous study showed *sunthi* (*Zingiber officinale*) reduces total cholesterol and serum LDL-cholesterol and also lowers the atherogenic index¹². *Trikatu* (*sunthi*, *maricha*, *pippali*) contains piperine has bio enhancer activity and it increased bio availability of other drugs, also decreases serum cholesterol and hepatic cholesterol.¹³ Ethanolic extract of *Plumbago zeylanica* (*chitrak*) showed significant reduction in serum total cholesterol, LDL cholesterol and triglyceride levels in albino rabbit.¹⁴ Previous study showed *vidanga* (*Emblia ribes*) decreases total cholesterol, LDL cholesterol, VLDL cholesterol and triglyceride¹⁵. *Musta* (*Cyperus rotundus*) contains activators of beta adrenoreceptors(AR), which is able to stimulate lypolysis and control weight gain.¹⁶ *Guggulu* has been recommended for the treatment of lipid disorders and its

complication. A series of experimental and clinical investigations conducted to know the anti-obesity and anti-atherosclerotic activity, showed *guggulu* effectively reduces serum cholesterol and triglycerides.¹⁷ *Trivrit* (*Operculina terpepethum*) contains α -turpethin and β -turpethin, has laxative action and used in the treatment of obesity as it decreases fat.¹⁸

The student 't' test (paired) showed statistically highly significant results by conventional criteria ($p < 0.001$) on body weight and body mass index (BMI).

The decrease in various body circumferences were statistically highly significant by conventional criteria ($p < 0.001$) in student paired 't' test. *Trivritayukta Navaka Guggulu* having, *katu rasa* (pungent taste), *laghu* (light), *ruksha* (dry) *guna* (properties), *ushna virya* (hot potency) and *katu* (pungent) *vipaka* (metabolism), *vatakaphashamaka* (specify *vata-kapha*), *karshana*, *lekhaniya* (bio-scrafer), *medorogahara* (destroy obesity), *amapachana* (digest metabolic toxins), *dhatu-shoshana* (absorbant) properties, which normalize the state of *agni* (digestive fire) and according to recent researches *guggulu* one of the ingredient of *Trivritayukta Navaka Guggulu*, may decrease hepatic steroid production, ultimately increasing the catabolism of plasma LDL cholesterol. Alternatively, the proposed active components of *guggulu*- *guggulsterones* E and Z, may increase hepatic binding sites for LDL cholesterol, thus increasing LDL clearance¹⁹ and also *maricha* (*Piper nigrum*) of

Trivritayukta navaka guggulu has hypolipidaemic action in rats.²⁰

Reduction was noticed in various skin fold thickness i.e. in biceps (9.46%), triceps(8.79%), scapular (7.13%), abdominal (10.89%) & thigh (8.12%). The results were highly significant by conventional criteria in paired 't' test (p<0.001). 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 that amount necessary for maintenance of life and reproductive functions, and storage fat consists of fat accumulation in adipose tissue, part of which protects internal organs in the chest and abdomen etc²¹; and exist various anthropometric methods for estimating body fat such as circumferences of various body parts or thicknesses of skinfolds²².

The reduction was observed in ESR (19.89%), FBS (1.17%), PPBS (0.72%), serum cholesterol (-0.86%), serum LDL (3.68%) & serum triglyceride (-14.98%). The results were insignificant (p>0.05). The increase in serum HDL-cholesterol was observed 4.61%, though statistically insignificant (p>0.05). The above data reveals that the drug has not shown encouraging results in respect to various biochemical parameters. When total effect of the treatment on subjective and objective parameter was taken into consideration, it was revealed that marked improvement was observed in 5.66% cases, moderate improvement in 30.19%, mild improvement in 39.62 % cases whereas 24.52% cases remained unchanged²³.

CONCLUSION

Trivrit yukta navaka guggulu is found to be potent drug for obesity evaluated clinically and from pharmacovigilance point of view no clinical adverse effect had been observed in any of the patients.

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