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Comparative clinical efficacy of *Tryushanadi Guggul* and *Navaka Guggul* in *Sthoulya* (Overweight)

Research Article

Ashvini D Pardhekar[1*], Sadhana Misar Wajpeyi[2], Shashank Gotarkar[3]

1.PG Scholar, 2.Professor, Department of Kayachikitsa,
Mahatma Gandhi Ayurved College, Hospital & Research Centre, Salod (H),
3. Assistant Professor, Department of Community Medicine, Jawaharlal Nehru Medical College Sawangi (M),
Datta Meghe Institute of Medical Sciences (Deemed to Be University), Sawangi (M), Wardha, Maharashtra. India.

Abstract

Sthoulya is *Medovahastrotodusthijanya Vyadhi*,which includes abnormal and excessive accumulation of *Medodhatu* in body. This is caused by lack of physical and mental activity,day dreaming,excessive intake of *Madhur*, *Snigdhaahar* results in increase *Kapha Dosha* and *Meda* which results in *Sthoulya*, which having symptoms of mild dyspnoea,thirst,drowsiness,excess sleep & appetite,offensive smell from the body,incapability to work and incapability to participate in sexual intercourseAim-Comparative Clinical Efficacy of *Tryushanadi Guggul* and *Navaka Guggul*in *Sthoulya*(Overweight) Material and Methods - Study comprisestotal 60 patients of *Sthoulya*randomly divided into two equal groups. Group A(Experimental group) was treatedwith 1 gm *Tryushanadi Guggul* two times a day after meal with Honey and Group B (Control group) was treatedwith 1 gm *Navaka Guggul* will administered two times a day after meal with Honey for 30 days. Patients were assessed for Subjective parameters like *Kshudrashwas*, *Swedadhikya*, *Atikshudha*, *Nidradhikya,* and Objective parameters like Body weight in Kg, Body Mass Index (BMI) in Kg/m^2, Waist Hip Ratio (WHR), and Mid Arm circumference (MAC) on 0,15, and 30th day, and Serum Lipid Profile was done on 0 and 30th day. Result – Significant improvement was observed inSubjective and Objective parameters. Conclusion –*Tryushanadi Guggul* is as effective as *Navaka Guggul* in the management of *Sthoulya* (Overweight). Hence *Sthoulya* can be effectively managed with *Tryushanadi Guggul.*

Key Words: *Sthoulya, Tryushanadi Guggul, Navaka Guggul*, Lipid profile.

Introduction

According to *Ayurveda*, *Sthoulya* is considered as *Santarpanottha Vyadhi* (caused due to overnutrition) mainly involving *Dushti* of *Medovahastrotasa*. It is a condition in which there is an abnormal increase and accumulation of *Meda*and *Mamsadhatu* levels in the body. *Atisthula*is one of the *AshtoninditaPurusha* according to *Acharya Charaka*.Excessive accumulation of *Meda* (Fat) and *Mamsa* of the body leads to enlargement of *Sphik*, *Udara,* and *Stana*.This improperly formed *Medo Dhatu* causes *Utsahahani* in the individuals, called *Atisthul*.

Lack of physical activity, daytime sleep, excessiveconsumption of*Kapha*and*Meda*aggravating food are *Hetu*(etiological factors) for *Sthoulya*. It can also cause due to *Beejaswabhava* (hereditary).All these *Hetus* causes derangement of *Agni*, which leads to *Ama* (undigested food) production in the body. This *Ama* causes *Medodhatvagnimandya*and *Strotorodha*. Due to the *Strotorodha,*there is an obstruction in *Vata,* thatmoves and stimulates *Agni(*digestive fire) in the *Koshtha*and causes *Atikshudha*(excessive hunger). *Medodhatvagnimandya* hampers the nourishment of successive *Dhatus*, so there is excessive production of *VikrutMedo Dhatu*, which gets accumulated in the body leading to *Sthoulya*. *Medas*(fat) obstructs all of the channels that continuously provide nutrients to other tissues, which hampers the formation of successive *Dhatu*(tissue)and only *Medas* accumulate in the body. (1) *Kshudrashwas* (dyspnoea on exertion), *Trishnadhikya* (excessive thirst), *Moha* (delusion), *Nidradhikya* (excessive sleep), *Krathana* (sudden obstruction to respiration), *Saad* (tiredness), *Atikshudha*, *Swedadaurgandha* (foul smelling of body), *Alpayu* (decreased life expectancy), and *Alpamaithuna* (decrease sexual potency) are all symptoms of *Sthoulya*. (2).

In modern medicine, *Sthoulya* is comparable to obesity. It is described as an abnormal deposition in adipose tissue with an increase in size or number (Hypertrophic obesity) or both.It is commonly measured in “Body Mass Index”(BMI). Value of BMI 25-29.9 kg/m^2 is considered overweight and 30 kg/m^{2}or more isconsidered obesity. (3)It is the fifth-largest cause

*** Corresponding Author:**
Ashvini D Pardhekar
PG Scholar, Dept. of Kayachikitsa, Mahatma Gandhi Ayurved College, Hospital & Research Centre, Salod (H), Datta Meghe Institute of Medical Sciences (Deemed to Be University), Sawangi (M), Wardha, Maharashtra. India.
Email Id: ashupardhekar@gmail.com

of death Worldwide. Approximately 1.9 billion adults aged 18 and over were overweight worldwide. Hypertension, Hyperlipidaemia, and glucose intolerance are the first detrimental effects to appear in a population in transition, while coronary heart disease and long-term sequelae of diabetes, such as Renal failure, appear many years or later. (4)

In *Ayurveda*, *Nidanparivarjana* (prevention of causative factors), *Shodhana* (purification procedure), and *Shamana Chikitsa* (internal medication) are described for *Sthoulya*.

For *ShamanaChikitsa*, many herbal formulations with *Tikta*, *Katurasa*, *Ushna*, *Rukshaguna*, *Kaphamedohara* and *Lekhana* properties are described which are effective in the management of *Sthoulya*, *Tryushanadi Guggul*is one of them described in *Bhavprakasha*.

Tryushanadi Guggul has ingredients like*Sunthi* (*Zingiber Officinalis* Roxb.), *Pippali* (*Piper longum*.Linn.), *Marich* (*Piper nigrum*.Linn.), *Vidanga* (*Embelia ribes*), *Musta* (*Cyperus rotundus* Linn), *Chitrak* (*Plumbago zeylanica*.Linn.), *Vacha* (*Acorus calamus* Linn.), and *Shuddha Guggul* (*Commiphora mukul*).(5)

Need of study

World Health Organization has identified overweight and obesity as a global epidemic.Obesity is more common in middle age, but it can strike anyone at any age. Women are more susceptible than men in most cases. In this age of modernization, the use of the latest technology in all aspects has resulted in significant changes in dietary habits, lifestyles, and various regimens of life. People who are attuned to a luxurious and comfortable lifestyle are more likely to be overweight or obese, which is associated with an increase in the risk of hypertension,Type 2 Diabetes mellitus, Coronary heart disease, and Hyperlipidemia like a metabolic disease,Arthritis,Infertility,and certain Cancers (In male-Colorectal cancers and in female-malignancy of Breast, Gall bladder, Endometrium and Cervix, Biliary tract in female).It is significantly increasing the risk of mortality at any age.Each year, almost 3.4 million adults die as a result of being overweight or obese.

In Modern medical science, drugs like Orlistat, and Sibutramine are used for obesity which reduces the absorption of food or causes suppression of appetite. Bariatric surgery is indicated in severe conditions.But all these have some limitations due to their side effects. So, this comparative research study is conducted to assesstheeffectiveness ofthe trial drug *Tryushanadi Guggul*in comparison withthe*Navaka Guggul*in*Sthoulya.* (6)

Aim and Objectives

Aim

Evaluation of Comparative efficacy of *Tryushanadi Guggul* and *Navaka Guggul* in the management of *Sthoulya*(Overweight).

Objectives

- To Evaluate the effect of *Tryushanadi Guggul* on Body Weight,Body Mass Index,Waist Hip Ratio,Mid Arm circumference,Serum Lipid Profile, and subjective parameters.
- To Evaluate the effect of *Navaka Guggul* on Body Weight,Body Mass Index,Waist Hip Ratio,Mid Arm circumference,Serum Lipid Profile, and subjective parameters.
- To compare the effect of *Tryushanadi Guggul* and *Navaka Guggul* on Body Weight,Body Mass Index,Waist Hip Ratio,Mid Arm circumference, Serum Lipid Profile, and subjective parameters.

Material and Methods

Source of Data: Total 60 patients, divided into Group A & Group B (30 patients in each group) reported to OPD and IPD of Kayachikitsa department, MGACH & RC Salod were enrolled for this study. Study was conducted after receiving Ethical clearance from Institutional Ethics committee of Datta Meghe Institute of Medical sciences, Sawangi (Ref no. MGACHRC/IEC/July-2020/61 dated 28/07/2020) as well as after CTRI registration (Reg. no. CTRI/ 2020/08/027376).

Study design**:** Randomized single-blind Standard controlled Trial

Study Type: Interventional Study

Inclusion criteria

- Patients willing to participate in the study and sign the consent form.
- Patients having the age between 20-40 years of bothgenders.
- Patients having B.M.I. between 25-30 kg/m2 with any of the cardinalsymptoms of *Sthoulya* mentioned in Ayurvedasuch as *Kshudrashwas* (Dyspnea on exertion), *Swedadhikya* (Excessive sweating), *Atikshudha* (Excessive hunger), *Nidradhikya* (Excessive sleep).

Exclusion criteria

- Patients with Body Mass Index (B.M.I) less than 25 and more than 30 kg/m2
- Patients having B.M.I. between 25-30 kg/m2 with deranged lipid level according to National Cholesterol Education Program Adult Treatment Plan III (7) and patients on medication for Dyslipidemia or on medication for Dyslipidemia.
- Known cases of Diabetes mellitus Type 2, Hypothyroidism, Kidney diseases, cardiovascular disorder and obesity caused due to drugs etc.
- Pregnant women and Lactating mothers.

Posology

- Group A- *Tryushanadi Guggul* 1gm twice a day orally after meal with honey for 30 days
- Group B- *Navaka Guggul* 1gm twice a day orally after meal with honey for 30 days
- *Pathyapathya*was advised for both groups in the form of *Ahar* (Dietary modification) and *Vihar* (Table no.1) on the basis of guidelines stated in the *Samhita*.

Table no. 1: Showing *Pathyapathya*

Ahar:

Timing	Diet Plan Note-Use Luke warm water for Drinking (At least 3.7 L/day for Men and 2.7 L/day For Women)
9 am -11 am	*Kulatha* (Horse gram)/*Mudga*(Green gram) (100 g) *Yusha* (Gruel) or Butter milk (200 ml) or Fruits like Papaya, Orange, Coconut water or Sprouted Bengal Gram /Mung Bean(100g)
1 pm	*Yava*(Barley) /*Jowara*(Sorghum)/Wheat chapatti (2)-50 gm Leafyvegetable-Spinach/Fenugreek/Amaranthus (100 gm) Other vegetable-Beans/Cabbage/Tomato(100 gm) Mixed Salad (Cucumber, Carrot, Radish
8 pm	*Yava* (Barley) /*Jowara* (Sorghum)/Wheat chapatti (2)-50 gm Leafy vegetable-Spinach /Fenugreek /Amaranthus (100 gm) Other vegetable-Beans/Cabbage/Tomato (100 gm) Mixed Salad (Cucumber, Carrot, Radish

Vihar-

- Waking up early morning.
- 30 minutes of brisk walking per day.

Composition of material

Table no. 2: Showing Ingredients of *Tryushanadi Guggul* (8)

Sr.No.	Ingredients	Botanical Name	Part Used	Quantity
1	*Sunthi*	*Zingiber officinaleRoxb*	Rhizome	1 part
2	*Marich*	*Piper nigrum*	Fruit	1 part
3	*Pippali*	*Piper longum Linn.*	Fruit	1 part
4	*Chitrak*	*Plumbago zeylanica Linn*	Root bark	1 part
5	*Musta*	*Cyperus rotundus Linn.*	Rhizome	1 part
6	*Vidanga*	*Embelia ribes*	Fruit	1 part
7	*Vacha*	*Acorus calamus Linn.*	Rhizome	1 part
8	*Shuddha Guggul*	*Commiphora mukul*	Gum resin	7 parts

Preparation of Material

Preparation of *Tryushanadi Guggul*

- In a stainless-steel container, 200 mg of fine powder of each ingredient except guggul was taken and properly mixed with 16 parts of water.
- Boil the water to reduce the decoction to 1/4th of the volume.
- Then guggul mixed with decoction in modern *Mawa* Machine and heat was applied continuously till it becomes solid.
- The completely dried material was crushed in a small bolus and kept in a tray appliedwith*Ghrita*andkeptinadrieron50^{0}Cfor6-7hrs.
- After this procedure, the bolus was finely powdered and added with magnesium stearate for binding the tablets
- Lastly, 250 mg tablets of *Tryushanadi Guggul* were prepared and packed in airtight container.

Assessment Criteria

Assessment was done on day 0,15, and 30.

a) Subjective

- *Kshudrashwas*
- *Swedadhikya*
- *Atikshudha*
- *Nidradhikya*

b) Objective

Anthropometric Assessment

- Body Weight in kg
- Body Mass Index (B.M.I.) in Kg/m^2
- Mid-arm circumference (MAC) in cm
- Waist-Hip Ratio (WHR) in cm

Investigation

- Lipid profilebefore and after treatment
- Fasting Blood Suger was done before treatment to exclude Diabetes melitus

Study Duration: 30 Days

Follow-up period: On Day 15 and 30

Gradation of Subjective parameters:

Assessment of Subjective parameters was done on day 0,15, and 30.

Table no. 3: Showing gradation of *Kshudrashwas*:

Even after heavy exertion, no dyspnea	**0**
Aftermoderate exertion dyspnea present, which subside later and is bearable; after climbing 10 steps upstairsdyspnea occurs, which takes more than 15 seconds.	**1**
Dyspnea after a short period of exertion, which is relieved and tolerable later; dyspnea after climbing 10 steps upstairs, which takes more than 25 seconds	**2**
Dyspnea after a short period of exertion, which is relieved later but is intolerable; dyspnea after climbing 10 steps upstairs, which takes more than 35 seconds.	**3**
Dyspnea in the resting state	**4**

Table no. 4: Showing gradation of *Atikshudha*: (350gm diet=1 meal)

Normal (2-3 meals)	**0**
Mild increased (normal diet with 1 meal extra)	**1**
Moderately increased (normal diet with 2 meals extra)	**2**
Severely increased (normal diet with 3 meals extra)	**3**

Table no. 5: Showing gradation of *Swedadhikya*

Sweating after heavy work and fast movement or in hot weather	**0**
Profuse sweating after moderate work and movement	**1**
Sweating after little work and movement (stepping ladder etc	**2**
Profuse sweating after little work & movement	**3**
Sweating even at rest or in cold weather	**4**

Table no. 6: Showing gradation of *Nidradhikya*

Normal sleep 6-8 hrs./day	0
Sleep more than 8-9 hrs./day with mild heaviness	1
Sleep more than 9-10hrs./day feeling heaviness with	2
Sleep more than 10hrs./day feeling heaviness with *Jrimbha* and *Tandra*	3

Statistical analysis

The Chi-square test, Student's paired and unpaired t-test, Mann Whitney U test, and Wilcoxon Signed Rank Test were utilized in the Statistical analysis, and software used in the analysis were SPSS 27.0 version and Graph Pad Prism 7.0 version. Descriptive and inferential statistics were used in Statistical Analysis and $p<0.05$ is considered as the level of significance.

Observation and Results

In the present study, demographic data showed that the disease was prevalent in the age group of 20-30 yearsof age, more in females(68.33%). In this study, the ratio of married and unmarried patients was found to be nearly equal. Regarding occupation, this study showed that56.67% of patients were studentsconsuming a mixed diet(83.33%). In this study, the ratio of married and unmarried patients was found to be nearly equal. It was observed that a family historyof obesity was absent in majority (66.67%) of patients in this study. Maximum patients were belonging to upper socio-economic status and 71.67% patients not performingany physical exercise. 73.33% patients had addiction of tea and taking diet 3 times per day. It was prevalent in *Pitta-Kaphaj Prakruti* with *Tikshna Agni.* In present study both groups showed significant results in reducing subjective parameters like *Kshudrashwas, Swedadhikya, Atikshudha, Nidradhikya* as well as objective parameters such as Body weight in Kg, Body Mass Index (BMI) in Kg/m^2, Waist Hip Ratio (WHR), Mid Arm circumference (MAC), and Serum Lipid Profile. except in high density lipoprotein. Hence both groups are effective in *Sthoulya.* In comparison no significant difference was observed. Hence both groups are equally effective in *Sthoulya* (overweight). In comparison, both groups showed equal effect in reducing total cholesterol and VLDL but regarding LDL and TG levels it was observed that*Navaka Guggul* was more effective than*Tryushanadi Guggul*. Regarding Overall improvement, out of 60 patients 51 (85%) patients showed excellent (>70%) relief and 9 (15%) patients showed moderate (30%-70%) relief.

Table no. 7: Comparison of *Kshudrashwas*in two groups

	Day 0	Day 15	Day 30
Group A	1.62±0.49	1.08±0.58	0.45±0.50
Comparison with baseline (Wilcoxon Signed Rank Test)			
z-value	-	5.21, P=0.0001, S	15.01, P=0.0001, S
Group B	1.76±0.52	1.12±0.60	0.60±0.50
Comparison with baseline(Wilcoxon Signed Rank Test)			
z-value	-	6.53 P=0.0001,S	15.50 P=0.0001,S
Comparison between two groups(Mann-Whitney U Test)			
z-value	0.00, P=1.00,NS	0.00, P=1.00,NS	0.00, P=1.00,NS

Table no. 8: Comparison of *Swedadhikya*in two groups

	Day 0	Day 15	Day 30
Group A	1.85±0.71	1.03±0.43	0.33±0.55
Comparison with baseline (Wilcoxon Signed Rank Test)			
z-value	-	6.80, P=0.0001,S	10.74, P=0.0001,S
Group B	2.03±0.58	1.11±0.50	0.37±0.56
Comparison with baseline (Wilcoxon Signed Rank Test)			
z-value	-	8.75, P=0.0001,S	12.74, P=0.0001, S
Comparison between two groups (Mann-Whitney U Test)			
z-value	1.07, P=0.28,NS	0.59, P=0.55,NS	0.27, P=0.78,NS

Table no. 9: Comparison of *Atikshudha* in two groups

	Day 0	Day 15	Day 30
Group A	1.57±0.50	0.96±0.56	0.24±0.43
Comparison with baseline (Wilcoxon Signed Rank Test)			
z-value	-	5.55, P=0.0001,S	14.98 ,P=0.0001,S
Group B	1.70±0.46	0.92±0.61	0.29±0.46
Comparison with baseline (Wilcoxon Signed Rank Test)			
z-value	-	7.00, P=0.0001,S	14.60, P=0.0001,S
Comparison between two groups (Mann-Whitney U Test)			
z-value	1.16, P=0.24,NS	0.26, P=0.79,NS	0.46, P=0.64,NS

Table no. 10: Comparison of *Nidradhikya* in two groups

	Day 0	Day 15	Day 30
Group A	1.05±0.23	0.66±0.48	0±0
Comparison with baseline (Wilcoxon Signed Rank Test)			
z-value	-	5.55, P=0.0001,S	14.98, P=0.0001,S
Group B	1.16±0.38	0.72±0.57	0.05±0.23
Comparison with baseline (Wilcoxon Signed Rank Test)			
z-value	-	3.68 P=0.002,S	14.57 P=0.0001,S
Comparison between two groups (Mann-Whitney U Test)			
z-value	1.04 P=0.29,NS	0.22 P=0.82,NS	1.00 P=0.31,NS

Table no. 11: Comparison of Body Weight in two groups

	Day 0	Day 15	Day 30
Group A	71.11±6.99	69.74±6.93	67.98±6.95
Comparison with baseline (Student's Paired t test)			
t-value	-	14.14, P=0.0001,S	20.55, P=0.0001,S
Group B	71.51±6.35	70.09±6.33	67.93±6.18
Comparison with baseline (Student's Paired t test)			
t-value	-	13.18, P=0.0001,S	10.67, P=0.0001,S
Comparison between two groups (Student's Unpaired t test)			
t-value	0.23, P=0.81,NS	0.20, P=0.83,NS	0.03, P=0.97,NS

Table no.12: Comparison of BMI (kg/m2) in two groups

	Day 0	Day 15	Day 30
Group A	27.46±1.57	26.96±1.60	26.26±1.63
Comparison with baseline (Student's Paired t test)			
t-value	-	12.66, P=0.0001,S	18.32, P=0.0001,S
Group B	27.60±1	27.06±1.09	26.33±1.05
Comparison with baseline (Student's Paired t test)			
t-value	-	12.33, P=0.0001S	20.42, P=0.0001S
Comparison between two groups (Student's Unpaired t test)			
t-value	0.40, P=0.68, NS	0.30, P=0.76, NS	0.20, P=0.83, NS

Table no.13: Comparison of Mid arm circumference (MAC) in two groups

	Day 0	Day 15	Day 30
Group A	31.63±2.28	31.02±2.14	29.43±5.43
Comparison with baseline (Student's Paired t test)			
t-value	-	5.83, P=0.0001,S	2.45, P=0.020,S
Group B	32.30±1.41	31.36±1.49	30.33±1.44
Comparison with baseline (Student's Paired t test)			
t-value	-	11.36, P=0.0001,S	19.37, P=0.0001,S
Comparison between two groups (Student's Unpaired t test)			
t-value	0.85, P=0.39,NS	0.30, P=0.76,NS	0.33, P=0.74,NS

Table no. 14: Comparison of Waist hip ratio Waist hip ratio (WHR) in two groups

	Day 0	Day 15	Day 30
Group A	0.87±0.06	0.87±0.06	0.86±0.05
Comparison with baseline (Student's Paired t test)			
t-value	-	3.00 P=0.005,S	4.18 P=0.0001,S
Group B	0.88±0.05	0.87±0.05	0.87±0.04
Comparison with baseline (Student's Paired t test)			
t-value	-	3.52 , P=0.001,S	5.86, P=0.0001,S
Comparison between two groups (Student's Unpaired t test)			
t-value	0.25, P=0.80,NS	0.17, P=0.86,NS	0.47, P=0.63,NS

Table no. 15: Comparison of Total Cholesterol in two groups

	Before t/t	After t/t	Student's t-test, t-value
Group A	172.43±16.16	158.76±16.54	7.28,p=0.0001,S
Group B	166.66±17.72	152.46±15.71	9.15,p=0.0001,S
Comparison between two groups (Student's Unpaired t test)			
t-value	1.31, P=0.19,NS	1.51, P=0.13,NS	

Table no. 16: Comparison of HDL in two groups

	Before t/t	After t/t	Student's t-test t-value
Group A	46.36±7.47	45.20±8.11	1.30, p=0.20,NS
Group B	49.20±6.46	48.10±5.51	1.29, p=0.20,NS
Comparison between two groups (Student's Unpaired t test)			
t-value	1.57, P=0.12,NS	1.61, P=0.11,NS	

Table no. 17: Comparison of LDL in two groups

	Before t/t	After t/t	Student's t-test t-value
Group A	103.43±14.79	92±15.21	7.97, p=0.0001,S
Group B	96.26±16.96	83.63±16.18	9.24, p=0.0001,S
Comparison between two groups (Student's Unpaired t test)			
t-value	1.74, P=0.08,NS	2.06, P=0.04,S	

Table no. 18: Comparison of VLDL in two groups

	Before t/t	After t/t	Student's t-test t-value
Group A	22.60±3.77	21.53±3.21	7.97, p=0.0001,S
Group B	21.20±4.05	20.50±3.25	9.24, p=0.0001,S
Comparison between two groups (Student's Unpaired t test)			
t-value	1.38, P=0.17,NS	1.23, P=0.22,NS	

Table no. 19: Comparison of Triglyceride(TG) in two groups

	Before t/t	After t/t	Student's t-test t-value
Group A	113.10±17.23	108.10±15.73	7.97, p=0.0001,S
Group B	106.93±19.70	102.16±16.17	9.24, p=0.0001,S
Comparison between two groups (Student's Unpaired t test)			
t-value	1.76, P=0.08,NS	3.57, P=0.001,S	

Table no. 20: Percentage of relief after treatment in *Tryushanadi Guggul* group

Relief criteria	No. of patients	Percentage of patients
Excellent (>70%)	26	86.67
Moderate (30%-70%)	4	13.33
Poor (<30%)	0	0
Total	30	100

Table no. 21: Percentage of relief after treatment in *Navaka Guggul* group

Relief criteria	No. of patients	Percentage of patients
Excellent (>70%)	25	83.33
Moderate (30%-70%)	5	16.67
Poor (<30%)	0	0
Total	30	100

Table no. 22: Percentage of relief after treatment in Total Patients

Relief criteria	No. of patients	Percentage of patients
Excellent (>70%)	51	85
Moderate (30%-70%)	9	15
Poor (<30%)	0	0
Total	60	100

Discussion

The study was conducted with the aim to assess"Comparative efficacy of *Tryushanadi Guggul* and *Navaka Guggul*in *Sthoulya* (Overweight)". As per *Ayurveda*, *Sthoulya* is known as *Santarpanottha Vikara*. *Meda* raises as a result of too much *Sneha* and *Madhurarasa*. *Sthoulya* is the outcome of *Shleshmavardhaka Ahara* and *Vihara,* which is caused by *Mandagni*. *Mandagni* leads to *Ama* (undigested food) production in the body. *Ama* causes *Strotorodha* which obstructs the normal movement of *Vayu* which moves into the *Koshta*and stimulates *Jatharagni* (digestive fire) leading to *Kshudhdhikya*(excessive hunger). *Medodhatvagnimandya* hampers the nourishment of successive *Dhatus*, so there is excessive production of *VikrutMedo Dhatu*,which gets accumulated in the body leading to *Sthoulya*.

This is a randomized comparative clinical study in which 60 patients of *Sthoulya*were selected and classified into two equal groups. The study started after getting approval from the Institutional Ethical Committee and clinical trial registry. Patients in Group A were treated with *Tryushanadi Guggul* 1gm with honey twice a day after meal and patients in Group B were treated with *Navaka Guggul*1gm twice a day after meal with honey for 30 days. Patients were assessed for Subjective parameters like *Kshudrashwas*, *Swedadhikya*, *Atikshudha*, *Nidradhikya,* and Objective parameters like Body weight in Kg, Body Mass Index (BMI) in Kg/m^2, Waist Hip Ratio (WHR), Mid Arm circumference (MAC), and Serum Lipid Profile. This trial enrolled a total of 60 patients, and all of them completed the treatment.

Kshudrash was showed statistically significant improvement after treatment in both groups and the comparison of both the groups was statistically insignificant (P=1.00,NS) after completion of treatment that is both groups are comparable and equally effective in reducing *Kshudrash was* as shown in table no.7. *Kshudrashwas* is caused due to *Strotorodha*. An increase in *Kapha Dosha* and *Meda Dhatu* is responsible for the derangement of *Agni* which causes. *Aam* formation in the body results in *Strotorodha*. This *Strotorodha* further causes *Kshudrashwas*. *Kaphamedohar, Agnidipana* and *Amapachan* properties of *Tryushanadi Guggul* helps in *Amapachana* and corrects deranged *Agni* which pacifies excess *Kapha* and *Meda* and hence causes *Srotoshodhana* thus helps in relieving *Kshudrashwas*

Swedadhikya showed statistically significant improvement after treatment in both groups and the comparison of both the groups was statistically insignificant (P=0.78,NS) after completion of treatment that is both groups are comparable and equally effective in reducing *Swedadhikya* as shown in table no.8. *Sweda* is the *Mala* of *Meda Dhatu*.In *Sthoulya*excessive increases in *Meda*and *Kapha* are responsible for *Swedadhikya. Tryushanadi Guggul* possesses *Lekhana* and *Kaphamedohar* property which may lead to the pacification of *Kapha Dosha* and *Meda* thereby relieving *Swedadhikya*.

Atikshudha showed statistically significant improvement after therapy in both groups, and the comparison of both the groups was statistically insignificant (P=0.64,NS) after completion of treatment that is both groups are comparable and equally effective in reducing *Atikshudha*as shown in table no.9.*Tryushanadi Guggul* possesses *Deepan, Pachan, Kaphamedohar,* and *Vatanuloman* properties. It helps in *Aampachan* which relieves *Strotorodha* and along with *Vatanuloman* property it alleviates the obstruction of *Koshtagata Vayu*. Thus, it is helpful in reducing *Atikshudha*.

Nidradhikya showed statistically significant improvement after therapy in both groups, and the comparison of both the groups was statistically insignificant (P=0.31 NS) after completion of treatment that is both groups are comparable and equally effective in reducing *Atikshudha*as shown in table no 10. *Kapha Dosha* causes *Atinidra* by its *Tamoguna. Tryushanadi Guggul* has *Kaphamedohar* property which reduces *Kapha* and *Tamo Guna*. Hence effective in reducing *Nidradhikya.*

In this study, BMI showed statistically significant improvement after treatment in both groups, and the comparison of both the groups was statistically insignificant (P=0.83 NS) after completion of treatment that is both groups are comparable and equally effective in reducing BMI as shown in table no 11. MAC showed statistically significant improvement after treatment in both groups, and the comparison of both the groups was statistically insignificant (P=0.74 NS) after completion of treatment that is both groups are comparable and equally effective in reducing MAC as shown in table no 12. In this study, WHR showed statistically significant improvement after treatment in both groups, and the comparison of both the groups was statistically insignificant (P=0.63 NS) after completion of treatment that is both groups are comparable and equally effective in reducing WHR as shown in table no 13.

Statistically significant reduction in all objective parameters like body weight, B.M.I.,Mid arm circumference and Waist-Hip Ratio was might be due to *Deepn*, *Vatanuloman, Kaphamedohar*, *Lekhana,* and *Sthoulyahar* properties of *Tryushanadi Guggul*. All these properties help in breaking the *Samprapti* of *Sthoulya* and reduce excess *Kapha* and *Meda* by *Lekhana* (scraping action) property of *Tryushandi Guggul* which causes a reduction in body weight, BMI, MAC, and WHR.

This study included patients having normal lipid levels. But the results showed a significant reduction intotal cholesterol, Low-Density Lipoprotein, Very Low-density lipoprotein, and Triglyceride and no improvement in High-density lipoproteinsin both the groups after completion of treatment. The reason for the reduction of lipid parameters might be due to the *Lekhana*and, *Kaphamedohar* properties of *Tryushandi* and *Navaka Guggul*. Regarding the comparison of LDLand TG, *Navaka Guggul* showed better improvement than *Tryushanadi Guggul* as it contains *Triphala* which is not present in *Tryushanadi Guggul.* Vaishali conducted a study on *Triphala* and showed

significant improvement in lipid levels.This may be due to *Triphala* having HMG-CoA reductase inhibitory action**.** (9)

Probable mode of action of Tryushnadi Guggul

Tryushanadi Guggul is indicated in the management of *Sthoulya* by *Bhavprakasha*. It contains *Sunthi* (*Zingiber officinale* Roxb.)*, Pippali* (*Piper longum* Linn.), *Marich* (*Piper nigrum* Linn.)*, Musta* (*Cyperus rotundus* Linn), *Vidanga* (*Embelia ribes*), *Chitrak* (*Plumbago zeylanica* Linn.), *Vacha* (*Acorus calamus* Linn.) and *Shuddha Guggul* (*Commiphora mukul*).

Most of the contents of *Tryushanadi Guggul* possesses *Katu, Tikta, Kashaya Rasa, Laghu, Tikshna, Ruksha, Ushna Guna, Katuvipaka,* and *Ushna Virya*. *Tikta*, *Katu Rasa*, and *Ushna Virya* have a dominance of *Agni* and *Vayu Mahabhoot* hence these drugs possess *Deepan, Pachan, Vatakaphahar, Vatanuloman, Lekhana, Chedana* and *Strotoshodhaka* properties. *Kashaya Rasa* and *Ushna, Tikshna, Ruksha Guna* causes *Rukshana* and *Shoshana* of excessive *Meda, Kapha,* and *Kleda.* In *Samprapti* of *Sthoulya,* there is *Kapha-Vata* dominance, *Agnidushti*, *Stotorodha*, *Vimargagaman* of *Vayu,* and *Apachita Meda Vruddhi*. *Vatakaphaghna* property of *Tryushanadi Guggul* helps in alleviating aggravated *Vata* and *Kapha Dosha. Agnideepana*(appetizer) property helps in normalizing deranged *Agni* and *Pachana* property causes *Amapachana*(digestive) by digestion of *Ama*. *Strotoshodhaka* property helps in removing an obstruction. *Vatanuloman* property helps in normalizing the movement of *Koshtagata Vayu*. *Lekhana* and *Chedana* property cause scraping action leading reduction of excessive accumulated *Meda* and *Kapha*. All these actions help in breaking the *Samprapti* of *Sthoulya*. *Musta, Vacha* and *Chitraka* are drugs of *Lekhaniya Mahakashaya* mentioned by *Acharya Charak*. These drugs and Guggul are mainly indicated in *Medoroga* due to their *Ruksha Guna* and *Lekhana* property. *Lekhana* property helps in reducing excess *Meda, Kapha* and *Kleda* thus effective in improving serum lipid levels. Various phytochemical studies conducted on these drugs showed the presence of phytochemicals having digestive, carminative, antiobesity, and antihyperlipidemic pharmacological actions which are mentioned at respective places. These properties are helpful in reducing the symptoms by breaking pathogenesis.

Trikatu comprises *Sunthi*, *Marich,* and *Pippali*in equal proportion.Piperine, 6-shogaol, and 6-gingerol are active components in *Trikatu* that have shown promising antihyperlipidemic effects and aid in lipid reduction. (10) *Trikatu* is effective in significant reduction of subjective and objective parameters due to the pharmacological effects of phytochemicals like piperine, which increase the secretion of digestive juices and catalyse the functioning of enzymes in the small intestine, so increasing metabolism and lowering obesity.(11)

Chitraka showed significant improvement in subjective parameters as well as objective parameters. *Plumbago zeylanica* having plumbagin and binaphthoquinonein roots. (12) These phytochemicals help in reducing lipid levels.

Various research studies are available on *Musta* showing its antiobesity, hypolipidemic, and antioxidant action. The rhizomes of *Musta*contain flavonoids, ascorbic acid, and polyphenol which show Anti-oxidant properties and scavenge free radicals fromthe body and reduce oxidative stress, and are helpful in reducing lipid levels. (13)

Vidanga is used in various formulations used in *Medoroga* showing a reduction in body weight as well as improvement in lipid levels. *Vidanga* showed significant improvement in subjective and objective parameters of *Sthoulya* due to pharmacological actions of chemical substances Embelin quercitol, tannin, and an alkaloid christembine present in it.

Vacha shows antiobesity and hypolipidemic action in various research studies conducted on it. β-asaron, a chemical constituent of *Vacha* (*Acorus calamus*) exerts anti adipogenetic activity by suppressing the expression of adipogenic transcription factors thus *Vacha*is effective in obesity.(14)

The proportion of *Guggul* in *Tryushanadi Guggul* is seven parts. Guggul is the main ingredients of many formulations used in *Medoroga* and *Sthoulya*. The active phytochemical guggulsteronesin guggul inhibit the farnesoid X receptor which is a bile acid receptor needed for the controlling the levels of cholesterol.The resins from the *Commiphora mukul* enhances the body's metabolic activity by improving thyroid function, increasing the body's fat-burning activity, and augmenting thermogenesis or heat production. (15) The research studies conducted on various ingredients of *Trushanadi Guggul* showed its efficacy in obesity and hyperlipidemia.

Probable mode of action of Navak Guggul

Navaka Guggul is used as control drug which comprised *Sunthi* (*Zingiber officinale.*Roxb.)*, Pippali* (*Piper longum.*Linn.), *Marich* (*Piper nigrum.*Linn.)*, Musta* (*Cyperus rotundus* Linn), *Chitrak* (*Plumbago zeylanica.* Linn.), *Amalaki* (*Emblica officinalis.* Burm)*, Haritaki* (*Terminalia chebula.*Retz.), *Bibhitaki* (*Terminalia belerica.* Roxb.)*, Vidanga* (*Embelia ribes*), and *Shuddha Guggul* (*Commiphora mukul*). Contents of *Navaka Guggul* are similar to *Tryushanadi Guggul*, but instead *Vacha* it contains *Triphala*.

Triphala contains 3 drugs, *Haritaki*, *Bibhitaki* and *Amalaki*in. equal quantity. *Triphala*has *Kashaya* dominance *Madhur, Amla*, *Tikta, Katurasa, Laghu, Ruksha guna, Ushnavirya*, *Madhur vipaka* and *Tridoshaharprabhava*. It helps inbalancing *Tridosha*. *Kashaya rasa, Laghu, Rukshaguna* of *Triphala* causes *Vatanulomana*.(16) *Tikta, Katu Rasa, Laghu, Ruksha Guna, Ushna Virya* helps in clearing the obstruction from *Strotas* by removing *Kapha* and *Meda*. *Lekhana* and *Kaphamedahar* properties causes reduction in excessive *Kapha*, *Meda*thus helps in breaking *Samprapti* of *Sthoulya*. Tannins, gallicacid, chebulinicacid, ellagicacid, and other bioactive substances such as flavonoids, saponins,

anthraquinones, aminoacids, fattyacids and different carbohydrates are found in *Triphala*. Due to which it has anti-obesity (Gallic acid), hypolipidemic, hypocholesterolemia, hypoglycemic, antihyperglycemic, insulin-releasing, anti-stress, antioxidant, andimmunomodulatory activities. (17) Cholesterol biosynthesis in the body is mainly maintained in the liver by the enzyme HMG-Co A and HMGR. *Triphala* contains tannins, gallic acid, chebulinic acid, ellagic acid, as well as other bioactive substances such flavonoids, saponins, anthraquinones, amino acids, fatty acids, and other carbohydrates. The enzymes HMG-Co A and HMGR are primarily responsible for maintaining cholesterol production in the body. HMG-CoA reductase is inhibited by *Triphala. Triphala* is high in fibers, which aid with digestion and bowel control. A reduction in cholesterol absorption may have resulted in considerable reductions in total cholesterol, LDL, Triglyceride, and VLDL in the current investigation. (18) Reduced absorption could be due to the oral administration of *Haritaki*, which has been shown to enhance stomach emptying. (19) Hence *Navaka Guggul* is effective in correcting lipid levels.

In this study, *Madhu* (Honey) was given as*Anupaan*in both groups, which potentiates the drug's action. It is effective in *Sthoulya* due to *Kashaya Rasa, Guru*, and *Ruksha Guna,* which act as *Tridosh shamak, Lekhana, and Medoghna.* Arshiya et.al. conducted comparative study on *Sthoulya* by using *Madhu Haritaki*and *Madhu Udak* for 90 days. *Madhu Haritaki* and *Madhu Udak* showed significant improvement in subjective and objective parameters. (20) Seema et.al. conducted comparative study on *Sthoulya* using (*Triphala+ Vidanga+ Musta Churna*) yoga with different *Anupan like Madhu Udak* in Group A and *Koshna Jala* in Group B. Result of this study showed better result in *Madhu Udak* group. (21)

In this study, both the groups were adviced lifestyle modification in the form of *Pathyapathya* of *Ahar* (Dietary modification) and *Vihar* (Waking up early morning and 30 minutes brisk walking). (22)

Conclusion

In present study both groups showed significant results in reducing subjective as well as objective parameters except high density lipoprotein. Hence both groups are effective in *Sthoulya.* In comparison no significant difference was observed hence both groups are equally effective in *Sthoulya* (overweight). A comparison of both groups showed no significant difference in lowering the Total Cholesterol and VLDL that is both groups are equally effective in reducing total cholesterol and VLDL but regarding LDL and TG levels it was observed that *Navaka Guggul* was more effective than *Tryushanadi Guggul*. Regarding overall improvement, an excellent (>70%) result was observed in a greater number of patients (86.67%) in group A treated with *Tryushanadi Guggul* than group B treated with *Navaka Guggul* (83.33 %). Hence it can be concluded that *Tryushanadi Guggul* is as effective as *Navaka Guggul* in the management of *Sthoulya* (Overweight) and *Sthoulya* can be effectively managed with *Tryushanadi Guggul.*

Conflict of interest

Authors declared no conflict of interest.

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