

**“A Randomized open controlled clinical trial of therapeutic effect of the oral administration of *Amrutadya guggul* in the management of *sthoulya* with special reference to *hyperlipidaemia* in age group 20-60 year”**

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**Abstract:** *Medoroga* is a disorder of *Medohara strotas* as per Ayurvedic concept characterised by deposition of *Meda* at the site of *Sphika* (buttocks), *Udara* (abdomen), *Stana* (breast) and all over body. The associated symptoms like *Kshudraswasa* (dyspnoea), *Trishana* (thirst), *Nidra* (sleep), *Kshudha* (hunger), *Sweda* (sweating), *Daurgandhya* (foul smelling), *Alpa maithun* (decreased libido) etc. are also found in this condition.

Obesity is a medical condition in which excess body fat has accumulated to extent that it may have an adverse effect on health leading to reduced life expectancy Increase health problems. body mass index a measurement which compare weight and height define as overweight (pre-obese) if BMI is 25-30 kg/m<sup>2</sup>, obese when BMI >30 kg/m<sup>2</sup>. Obesity is most common nutritional disorder not even in affluent societies but even in middle class change in the dietary habits, behaviour pattern & sedentary life most probable cause of this disease.

**Aim and Objective:** A Randomized controlled trial to evaluate the efficacy of *Amrutadya Guggulu* in the management

of *Sthoulya* with special reference to *Hyperlipidaemia*.

**Material & Methods:** Total 70 patients of *Sthoulya* selected randomly, which is then divided into two equal group i.e. 35 patients in each group. Giving intervention by *Amrutadya Guggulu* in group A and *Navak Guggulu* in group B for 45 day's treatment and followed up taken for therapy 45 days. Analysis of all patients were done and after that result and conclusion were drawn.

**Result and Conclusion:** *Amrutadya Guggulu* and *Navak Guggulu* both are effective in the management of *sthoulya* to reduce sign, symptoms. On the basis of overall percent relief, *Navak Guggulu* has found more effective than *Amrutadya Guggulu* in the management of *Sthoulya*.

**Keywords:** *Sthoulya*, *Amrutadya Guggulu*, *Navak Guggulu*, Obesity.

**Introduction:** In Ayurveda, *Medoroga* has been dealt by different Acharyas in reference to its cause, sign and symptoms, complications, prognosis and management. Acharya *Charak* has described it in *Ashtanindita purusha* (eight despicable persons) *Charaka* categorised this problem under *Santarpaniyajanit vyadhi*. While Acharya

*Sushruta* considers *sthoula* as sadatur because sthoulya needs regular and continuous care and prevention is the best of management. *Sushruta* explain Medoroga in *doshdhatuvruddhikshay vidnyaniyaadhyay*. *Acharya vaghbhta* explain *Medoroga in dwidhupkarniya adhikya* in which sthoulya is *apatarpaniya vyadhi*. Recent studies have reported that high cholesterol is present in 25-30% of urban and 15-20% rural subjects. This prevalence is lower than high income countries. Hyperlipidaemia (*Medoroga*) is the condition of abnormally elevated level of any or all lipids and /or lipoproteins in the blood<sup>8</sup>. Lipids and lipoproteins abnormalities are regarded as a modifiable risk factor for CHD/CVD due to their influence on atherosclerosis<sup>9</sup>. Nowadays, *hyperlipidaemia (Medoroga)* has become a burning problem. A number of herbals, mineral and herbo-mineral medicines are described in various ancient texts of Ayurveda for treating *hyperlipidaemia (Medoroga)*

*Medoroga* is a disorder of *Medohara strotas* as per *Ayurvedic* concept characterised by deposition of Meda at the site of *Sphika* (buttocks), *Udara* (abdomen), *Stana* (breast) and all over body. The associated symptoms like *Kshudraswasa (dyspnoea)*, *Trishana* (thirst), *Nidra* (sleep), *Kshudha* (hunger), *Sweda* (sweating), *Daurgandhya* (foul smelling), *Alpa maithun* (decreased libido) etc. are also found in this condition.

#### **Aim and Objective:**

##### **1. Primary Objective:**

- To study the efficacy of *Amrutadya Guggulu* on *Sthoulya* on the basis of symptoms & bad cholesterol (LDL), VLDL, T Cholesterol, S. Triglycerides level in the blood

##### **2. Secondary Objectives:**

- To compare the efficacy of *Amrutadya Guggulu* and *Navak Guggulu* on the basis of symptoms and lipid profile
- To study the changes in anthropometric parameter BMI at 0 and at the end of 12 weeks.

#### **Materials and Methods:**

**Study Design:** Prospective, Randomized, Controlled, open labelled clinical study

**Place:** PG Department of *Kayachikitsa*

**Duration:** 45 days' drug intervention and 45 days follow up.

#### **Selection of Patient:**

##### **Inclusion Criteria:**

1. Subjects will be selected specially according to increased BMI(25-30)& increased LDL >130 mg/dl
2. Subjects of either sex (both males & females), any caste, religion in the age group of 20 to 60 yrs.
3. Subjects willing to follow the procedures as per the study protocol and voluntarily sign an informed consent form.
4. The subject having classical symptoms of sthoulya according to *chrakacharya Daurbalya, Daurgandhya, Adhikipipas, Adhikakshudha, Swedadhikeya, Kshudraswasa, Kruchyavyavay*

##### **Exclusion Criteria:**

1. Subjects not willing for trial.
2. Age less than 19 and more than 60
3. Subjects with Diabetes Mellitus Type 1 and Type 2, hypogonadism, Cushing, syndrome, PCOD
4. Subject having taking medicine like tricyclic antidepressant, *sulphonylureas*, oral contraceptive pills, corticosteroids, sodium valproate.

5. Subjects with uncontrolled Hypothyroidism or Hyperthyroidism.
6. Known cases of Severe/Chronic hepatic or renal disease/HIV.
7. Known subject of any active malignancy.
8. Subjects giving history of significant cardiovascular event < 12 week-prior to randomization.
9. Subjects ECG demonstrating any signs of uncontrolled arrhythmia/acute ischemia.
10. Pregnant and lactating females.
11. Subjects currently participating in any other Clinical Study.

12. Any other medical or surgical condition considered unsuitable for patient participation in the study as per investigator's judgement

#### 4)Withdrawal criteria

1. Progressive worsening of disease & development of complication during trial.
  2. Patients who do not complete the trial duration with follow Up.
  3. Death of patient due to any cause.
- Non – co-operative behaviour of the patients.

#### Treatment Details:

Group	GROUP A	Group B
No.of Patients	35	35
Treatment	Amrutadya Guggulu	Navak Guggulu
Dose	2 gm	2 gm
Kalpana	Vati	Vati
Duration	45 days therapy and post therapy 45 days follow-up	45 days therapy and post therapy 45 days follow-up
Time administration	Vyanodane	Vyanodane
Route	Oral	Oral

#### Assessment Criteria:

##### Observation and criteria for graduation of disease

##### 1)Loss of libido (*kruchravyava*)

Never	Grade 0
Occasionally	Grade 1
Intermittent	Grade 2
Always	Grade 3

##### 2)Tiredness (*Daurbalya*)

After 2km walk	Grade 0
After 1km walk	Grade 1
After ½ km walk	Grade 2
During routine work	Grade 3

##### 3)Bad body odour (*Daurgandhya*)

Absent	Grade 0
Feeling after moderate work	Grade 1

Feeling after slight work	Grade 2
Feeling even in	Grade 3

4) Excessive sweating (*Sweda adhikya*)

No sweating	Grade 0
Profuse sweating after moderate work	Grade 1
Profuse sweating after slight work	Grade 2
Sweating even in resting condition	Grade 3

5) Excessive hunger (*Adhika Kshudha*)

Feel hunger in next meal only	Grade 0
Feel hunger for once in between meals	Grade 1
Feel hunger for more than twice	Grade 2
Feel hunger always	Grade 3

6) Excessive thirst (*Adhika Pipasa*)

Normal thirst	Grade 0
Upto 1 litre excess intake of water/fluid	Grade 1
Upto 2-3 litre excess intake of water/fluid	Grade 2
Grade 1	
More than 3 litre intake of fluid	Grade 3

7) Dyspnoea on exertion (*Kshudraswasa*)

Absent	Grade 0
Dyspnoea on moderate work	Grade 1
Dyspnoea on slight work	Grade 2
Dyspnoea on rest	Grade 3

**C) Objective criteria**

Lipid profile

Initial Lipid level

Blood Lipid level	Before trial
LDL	
VLDL	
HDL	
S. triglycerides	
S. Cholesterol	

After 90 days

Blood Lipid level	After trial
LDL	
VLDL	

HDL	
S. triglycerides	
S. Cholesterol	

## BMI

Before trial	
After trial	

**Observation and Result:****% Relief in Group A & Group B (Table no. 79):**

Trial Group			Control Group		
SR NO.	CR NO	% Relief	SR NO.	CR NO	% Relief
1	10362	12.50	1	12001	14.29
2	10895	25.00	2	12002	37.50
3	11222	20.00	3	37965	33.33
4	11647	66.67	4	38277	50.00
5	12780	80.00	5	38465	45.45
6	12847	50.00	6	38466	42.86
7	13106	33.33	7	38644	42.86
8	13941	40.00	8	38643	16.67
9	16492	50.00	9	38852	37.50
10	16634	50.00	10	38992	66.67
11	19694	33.33	11	38991	42.86
12	20434	30.00	12	39044	57.14
13	20433	55.56	13	39154	14.29
14	20678	44.44	14	39155	42.86
15	20677	33.33	15	39152	25.00
16	21683	36.36	16	39341	14.29
17	21678	16.67	17	39342	14.29
18	21680	0.00	18	39343	20.00
19	27335	0.00	19	39446	40.00
20	27336	18.18	20	39445	0.00
21	27432	14.29	21	39548	0.00
22	27956	22.22	22	39547	0.00
23	26370	20.00	23	39686	0.00
24	30553	25.00	24	39687	0.00
25	30654	30.00	25	39801	25.00
26	31242	33.33	26	39797	12.50

27	32765	25.00	27	39798	37.50
28	34185	40.00	28	40133	75.00
29	33496	25.00	29	40148	40.00
30	40400	20.00	30	40150	0.00
31	40397	40.00	31	40132	25.00
32	40518	20.00	32	40244	25.00
33	40706	16.67	33	40206	0.00
34	40705	37.50	34	40282	37.50
35	40765	44.44	35	40399	28.57
Symptoms	Percentage Relief				
	Group A		Group B		
Tiredness ( <i>Daurbalya</i> )	23.81		25.00		
Bad body odors ( <i>Daurgandhya</i> )	33.33		27.59		
Excessive sweating ( <i>Swedadhikya</i> )	36.59		26.92		
Excessive hunger ( <i>Adhika kshudha</i> )	33.33		18.92		
Excessive thirst ( <i>Adhika pipasa</i> )	47.22		32.26		
Dyspnoea on exertion ( <i>Ayasa Shwas</i> )	26.79		38.00		

**Overall effect of therapy according to subjective criteria on 70 patients of *Sthoulya w. s. r. to Hyperlipidaemia***

Result	Group A		Group B	
	Number of patients	%	Number of patients	%
Marked improvement (75 to 100 %)	12	34.29%	14	40.00%
Moderate improvement (50 – 75 %)	17	48.57%	17	48.57%
Mild improvement (25 – 50 %)	5	14.29%	3	8.57%
Unchanged (0 to 25 %)	1	2.86%	1	2.86%

In **Group A of Amrutadya guggul** out of 35 patients, marked improvement (75 to 100 % relief) was noted in 12 patients i.e. 34.29 %, Moderate Improvement (50 to 75 % relief) was noted in 17 patients i.e. 48.57 %, No Improvement (0 to 25 %

relief) was noted in 5 patients i.e. 14.29 % and Mild Improvement (25 to 20 % relief) was noted in 1 patient i.e. 2.86 %.

In **Group B of Navak guggul** out of 35 patients, marked improvement (75 to 100 % relief) was noted in 14 patients i.e. 40

%, Moderate Improvement (50 to 75 % relief) was noted in 17 patients i.e. 48.57 %, Mild Improvement (25 to 50 % relief) was noted in 3 patients i.e. 8.57 % and Mild Improvement (25 to 20 % relief) was noted in 1 patient i.e. 2.86 % in this study.

### Discussion on statistical analysis

Statistical Analysis: In Trial Group and In Control Group

Parameters (By Mann-Whitney test Test)  
A) Subjective

Mann-Whitney test was applied to both groups separately to observe whether the difference between D0 and D90 score is significant or not.

### Mode of action (Amrutadya Guggulu)

*Amrutadya Guggulu* is a *aushadha yoga* explained under *medoroga chikitsa adhyay* of *Bhaishajyaratnavali*. It contains *Amruta, Ela, Vidanga, Kutaj, Haritaki, Bibhitaki, Amalaki, Guggulu*. Thus the largest ingredient is *Guggulu* which possess *Tikta, katu rasa, ushna virya, katu vipaka, ruksha, laghu, tikshna, vishad, sar, sugandhi guna* which is excellent *kapha pitta shamaka*. *Hyperlipidemia* if seen through the lens of Ayurveda, may be taken as *medo dosha*, as *bahu abaddha medas* which circulates all over the body. *Ruksha guna, katu vipaka, kashaya rasa* causes *medovilayana*. The drugs such as *Amruta, haritaki, Bibhitaki, Amalaki, Guggulu* are *rooksha, sookshma and ushna* in nature thus penetrating into the deeper channels and removing *sanga/obstruction*. In case of *hyperlipidemia*, obstruction may be seen as *atherosclerosis* seen due to deposition of fat in arteries. Hence by the virtue of above properties, *thelps* in

liquefaction of these fatty blockages. Hence by virtue of above properties, the *samprapti vighatana* is done Therefore the drug *Amrutadya Guggulu* which possesses *medohara* and anti hyperlipidemic property is opted for this study.

### Conclusion:

The effect of *Amrutadya guggul* (Group A) is not significant than *Navak guggul* (Group B) for subjective criteria – Tiredness (*Daurbalya*), Bad body odors (*Daurgandhya*), Excessive sweating (*Swedadhikya*), Excessive hunger (*Adhika kshudha*), Excessive thirst (*Adhika pipasa*) and Dyspnoea on exertion (*Ayasa Shwas*). The effect of *Amrutadya guggul* (Group A) is not significant than *Navak guggul* (Group B) for objective criteria such as Weight, BMI, LDL, HDL, VLDL Sr. Cholesterol and Sr. Triglycerides.

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