



Research Article

A RANDOMIZED CLINICAL TRIAL OF NAVAKA GUGGULU IN STHAULYA

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ABSTRACT

Acharya Charaka has quoted *Sthaulya* under the eight varieties of impediments which are designated as *Ashtaunindita Purusha*, *Ati-Sthaulya* comprises one of them. *Acharya Charaka* also listed this problem under *Santarpanajanita Vyadhi*. According to *Acharya Charaka* basic treatment principle of *Sthaulya* is '*Guru Apatarpana*'. *Navaka Guggulu* is a polyherbal formulation initially depicted by *Acharya Chakrapani* in his text *Chakradutt*, written in 11th century, under *Medoroga*. **Aim & Objectives:** The perception of the present study is to find out the clinical effect of *Navaka Guggulu* on *Sthaulya*. **Material and Methods:** To assess its therapeutic efficacy on *Sthaulya*, a clinical study was performed. Total of 21 patients of *Sthaulya* were selected randomly. Selection of patients was done on detailed clinical history, physical examination and other necessarily desired investigations irrespective of their gender, age and caste. **Statistical Analysis:** To obtained data of the clinical study, Efficacy of the therapy of *Navaka Guggulu* was statistically determined by Wilcoxon Signed Rank test and Paired t-test analysis. **Results:** On the basis of subjective and objective parameters, *Navaka Guggulu* shows positive result in the management of *Sthaulya*. **Conclusion:** *Navaka Guggulu* is found effective against *Sthaulya* by a randomized clinical trial.

INTRODUCTION

Navaka Guggulu^[1] is an unique polyherbal formulation containing *Guggulu* (*Commiphora wightii*) as the main ingredient. Its constituents possess *Ruksha*, *Lekhan*, *Chhedan*, *Medoghna* and *Vatakaphahara* properties. The same formulation is named as *Vyoshadi Guggulu*,^[2] *Dashanga Guggulu*^[3] and *Trayushnadi Guggulu*^[4] in different classics. Formulations which contain *Guggulu* as the main ingredient can be called as *Guggulu Kalpana*. It is used in formulations for both purposes, as a base and as well as medicament. While describing the property of *Guggulu*, *Acharya Sushruta* mentioned "*Puran*" *Guggulu* is '*Medohara*' as it has the quality of "*Apakarshana*".^[5] Various researches reveal that it lowers cholesterol and triglycerides, while maintaining the HDL and LDL.^[6]

Sthaulya is one of the major lifestyle disorders that are prevalent nowadays. It comes under the category of *Santarpanottha Vyadhi* as well as in *Medopradoshaja Vikara* in *Charaka Samhita*^[7] and as *Ras-Nimittaj Vikara* in *Sushruta Samhita*^[8]. According to *Acharya Charaka* basic treatment principle of *Sthaulya* is '*Guru Apatarpana*'. In this context *Teekshna*, *Vata-Kaphahara* and *Medohara* drugs are recommended for *Sthaulya*. Considering all these, attempt was made to evaluate clinical efficacy of *Navaka Guggulu* in *Sthaulya*.

MATERIALS AND METHODS

Raw Drug Authentication

- ❖ *Guggulu*, exudate of *Commiphora wighitti* was purchased from forest Department, Una (Himachal Pradesh) subjected to authentication from Dravyaguna department of Rishikul Campus, Haridwar, UAU, as per API protocol and Analytical lab of Vasu Research Centre, Vadodara, Gujarat.
- ❖ Fresh *Go-Mutra* was procured from Rishikul Campus Haridwar.
- ❖ Dry *Triphala*, *Trikatu*, *Trimad* were purchased from Hansa Pharmacy of Haridwar, and subjected to

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authentication from Dravyaguna department of Rishikul Campus, Haridwar.

Shodhana of Guggulu⁽⁹⁾

Physical impurities like stone, bark, wood etc. from raw material were removed manually. *Asudhha Guggulu* was broken into small pieces and taken in the *Pottali* (bundled in cotton cloth). It was hanged in *Dola Yantra* (an instrument used to impregnate medicine in liquids) in *Gomutra* taken in a Steel vessel. *Gomutra* was heated at a temperature between 75°C- 85°C until all the *Guggulu* was passed into the fluid through the cotton cloth. After complete filtration, the filtrate was subjected for further heating to evaporate the liquid up to the semisolid state. During the whole process temperature was maintained between 75°C-85°C, Later it was shifted into a stainless steel tray. The mass

was dried in sunlight and then pounded with a pestle in a stone mortar and preserved for further use.

Method of preparation of Navaka Guggulu

Shuddha Guggulu was heated and the fine powder of *Triphala*, *Trikatu*, *Trimad* were mixed with *Guggulu*. Gum acacia in 9% concentration of the mixture was taken in a beaker and sufficient amount of water was poured into it. The content was heated on hot plate till a homogenous solution was obtained. This solution was added to the mixture and mixed thoroughly in a stainless-steel vessel and pass through sieve no. 22 to obtain granules. These granules were dried in hot air oven for one day at 50°C temp. After that, the granules were compressed into tablets with the help of 12 station tablet punching machine. It was stored in an airtight container.

Table 1: Formulation composition of Navaka Guggulu

| No. | Ingredients | Latin Name | Part used | Proportion |
|-----|------------------|----------------------------------|----------------|------------|
| 1. | <i>Haritaki</i> | <i>Terminalia chebula</i> Retz | Dried Pericarp | 1 part |
| 2. | <i>Bibhitaki</i> | <i>Terminalia belerica</i> Roxb. | Dried Pericarp | 1 part |
| 3. | <i>Amalaki</i> | <i>Phyllanthus emblica</i> Linn. | Dried Pericarp | 1 part |
| 4. | <i>Shunthi</i> | <i>Zingiber officinale</i> Roxb. | Dried Rhizome | 1 part |
| 5. | <i>Marich</i> | <i>Piper nigrum</i> Linn. | Dried Fruit | 1 part |
| 6. | <i>Pippali</i> | <i>Piper longum</i> Linn. | Dried Fruit | 1 part |
| 7. | <i>Musta</i> | <i>Cyperus rotundus</i> Linn. | Dried Rhizome | 1 part |
| 8. | <i>Vidanga</i> | <i>Embelia ribes</i> Burm. | Dried Fruit | 1 part |
| 9. | <i>Chitraka</i> | <i>Plumbago zeylanica</i> Linn. | Dried Root | 1 part |
| 10. | <i>Guggulu</i> | <i>Commiphora wightii</i> | Exudate | 9 parts |

Selection of Patients

Total 21 patients of *Sthaulya* were selected from the O.P.D./I.P.D. of Rishikul Govt. PG Ayurvedic College and Hospital, Haridwar. The clinical study was started after obtaining Institutional Ethics Committee clearance (UAU/RC/IEC/2018-19/04 dated-30/10/2018) and Registered at Clinical Trial registry of India, ICMR, New Delhi, vide CTRI/2019/03/018149 [Registered on 18/03/2019].

Inclusion Criteria

1. The patients whose age above 15 and below 50 years was selected.
2. The patients were having clinical signs and symptoms of *Sthaulya*.
3. B.M.I criteria were also followed for selection of patient. (BMI >25kg/m²)

Exclusion Criteria

1. Patients with hypothyroidism & Cushing syndrome.
2. Patients with long term steroid treatment.
3. Patients with severe hypertension.

4. Patients with evidence of renal, hepatic and cardiac involvement.

5. Patients with diabetes mellitus.

Other systemic diseases which intervene with the course of treatment.

Drug, Dose and Duration

Navaka Guggulu- 1gm TDS with lukewarm water after chewing before meal for the duration of 90 days.

Investigations

The following investigations were carried out for the exclusion of the patients before starting the trial and to access any adverse effect of the drug over the patients at the end of the trial.

1. Routine haematological, urine examination
2. Lipid profile
3. Kidney profile
4. Liver profile
5. Thyroid profile
6. Blood sugar level

Assessment criteria

Classical signs and symptoms of *Sthaulya* such as *Snigdhatva* (greasiness), *Pipasadhikya* (excessive thirst), *Nidradhikya* (excessive sleep), *Javoprodh* (hampered movements), *Kshudhadhikya* (increased appetite), *Swedadhikya* (over sweating), *Daurbalya* (debility) and *Daugandhya* (foul smell) were taken as subjective criteria. Multidimensional scoring pattern [Table 2] was adopted to assess the response of trial

drugs objectively and for statistical analysis. This score was obtained before and after the treatment, and percent relief was calculated to assess the efficacy of therapy. Biochemical investigations (serum cholesterol, serum triglyceride, high-density lipoprotein [HDL], LDL and VLDL) changes in weight, BMI, waist-hip ratio and thickness of skin fold were considered as objective criteria and analyzed before and after the treatment.

Table 2: Grading Criteria of Subjective Parameter

| Criteria | 0 | 1 | 2 | 3 |
|-------------------------------|--|--|--|--|
| <i>Chalatva</i> | <i>Achalatva</i> | <i>Alpachalatva</i> (in areas) after fast movement | <i>Alpachalatva</i> (in areas) even after movement | <i>Chalatva</i> (in areas) after mild movement |
| <i>Daurbalya</i> | Able to do routine work without difficulty | Able to do moderate exercise without difficulty | Able to do only mild exercise | Able to do mild exercise with difficulty |
| <i>Swedadhikya</i> | <i>Sweda</i> after heavy work & fast movement | <i>Atisweda</i> after moderate work & movement | <i>Sweda</i> after little work and movement | <i>Atisweda</i> after little work and movement |
| <i>Pipasatiyoga</i> | <i>Swabhavik pipasa</i> (want two litre water) per day | Up to 1 litre excess intake of water per day | 1-2 litre excess intake of water per day | 2-3 litre excess intake of water per day |
| <i>Kshudhatimatra</i> | <i>Swabhavik kshudha</i> | <i>Kshudha</i> more than normal | Willing towards only most liking food not to others | Willing towards only one <i>Madhur rasa</i> food stuff |
| <i>Nidradhikya</i> | <i>Swabhavik Nidra</i> 6-7 hrs/day | <i>Nidra</i> up to 8 hrs/day | <i>Nidra</i> up to 8 hrs/day with day sleep one hrs | <i>Nidra</i> up to 10 hrs/day with day sleep two hrs and <i>Tandra</i> |
| <i>Snigdhatva</i> | Normal <i>snigdhatva</i> | <i>Snigdhatva</i> of body in summer season | <i>Snigdhatva</i> of body in dry season | Excessive <i>Snigdhatva</i> of body in dry season |
| <i>Sarvakriya Asamarthata</i> | <i>Swabhavik kriya samarthata</i> | <i>Kriya samarthata</i> late in time | <i>Kriya samarthata</i> late in time with lot of mental pressure | Not starting work or doing little work very slowly |

Statistical Analysis

The data obtained in clinical study was subjected to statistical tests and calculated on the basis of percentage of improvement in each parameter. Wilcoxon Signed Rank Test was applied to evaluate the effect of therapy on the subjective parameters and paired t-test was applied on objective parameters. The tests were carried at the 0.05 < 0.01 < 0.001 level of the p-value.

OBSERVATION & RESULT

Maximum numbers of patients (23.80%) were from the age group of 26–30 years, female (85.71%), married (71.42%), and Hindu (95.23%) by religion. Maximum patients were having *Kapha Vata Prakriti*

(61.90%) *Madhyama Sara* (66.66%), *Madhyama Satva* (42.85%), *Madhyama Samhanana* (57.14%), *Madhyama Pramana* (61.90%), *Madhyama Satmya* (61.90%), *Avara Vyayama Shakti* (47.61%), *Madyama Ahara Shakti* (52.38%), *Rajasika Manas Prakriti* (76.19%), sound sleep (57.14%), and *Madhyama Koshta* (57.14%) were found in maximum patients. Maximum numbers of patients (42.85%) were from the BMI of 30–35, educated (85.71%), vegetarian diet (76.19%) were found in maximum patients.

Subjective Parameters

Test Procedure- Wilcoxon Signed-Rank Test on Subjective Parameters.

Table 3: Subjective Parameters

| Parameters | Median | | Wilcoxon Signed Rank W | P-Value | % Effect | Result |
|------------------------------|--------|-----|------------------------|---------|----------|-------------|
| | BT | AT | | | | |
| <i>Chalatva</i> | 2 | 1 | -4.065 ^a | 0.00 | 63.89 | Significant |
| <i>Daurbalya</i> | 2 | 1 | -4.300 ^a | 0.00 | 61.11 | Significant |
| <i>Swedadhikya</i> | 1 | 0.5 | -3.690 ^a | 0.00 | 62.96 | Significant |
| <i>Pipasatiyoga</i> | 2 | 1 | -3.945 ^a | 0.00 | 61.29 | Significant |
| <i>Kshudhatimatra</i> | 1 | 1 | -4.025 ^a | 0.00 | 62.07 | Significant |
| <i>Nidradhikya</i> | 1.5 | 1 | -3.879 ^a | 0.00 | 62.50 | Significant |
| <i>Snigdhatta</i> | 1 | 1 | -3.900 ^a | 0.00 | 60.71 | Significant |
| <i>SarvakriyaAsamarthata</i> | 2 | 1 | -4.264 ^a | 0.00 | 62.50 | Significant |

Since observations are on an ordinal scale (gradations), we have used the Wilcoxon Signed Rank test to test efficacy. From the above table, we can observe that P-Values are less than 0.05. Hence, we conclude that the effect observed is significant.

Objective Parameters

Test Procedure- Paired t-test on Objective Parameters.

Table 4: Objective Parameters

| Group A | | Mean | N | SD | SE | t-Value | P-Value | % Effect | Result |
|-----------------------|----|--------|----|-------|------|---------|---------|----------|--------|
| Body Mass Index | BT | 31.59 | 20 | 2.69 | 0.60 | 9.661 | 0.000 | 3.90 | Sig |
| | AT | 30.36 | 20 | 2.81 | 0.63 | | | | |
| Body weight | BT | 84.20 | 20 | 11.83 | 2.64 | 12.473 | 0.000 | 3.55 | Sig |
| | AT | 81.21 | 20 | 12.01 | 2.68 | | | | |
| Mid Arm Circumference | BT | 35.04 | 20 | 7.22 | 1.61 | 18.200 | 0.000 | 5.39 | Sig |
| | AT | 33.15 | 20 | 7.05 | 1.58 | | | | |
| Waist Circumference | BT | 103.27 | 20 | 4.99 | 1.11 | 11.655 | 0.000 | 2.48 | Sig |
| | AT | 100.70 | 20 | 5.10 | 1.14 | | | | |
| Hip Circumference | BT | 108.63 | 20 | 8.48 | 1.90 | 5.456 | 0.000 | 3.29 | Sig |
| | AT | 105.05 | 20 | 8.52 | 1.91 | | | | |
| Skin Fold Thickness | BT | 3.72 | 20 | 0.96 | 0.21 | 15.858 | 0.000 | 20.19 | Sig |
| | AT | 2.97 | 20 | 0.96 | 0.21 | | | | |
| Waist Hip Ratio | BT | 0.95 | 20 | 0.06 | 0.01 | -1.761 | 0.034 | 1.48 | Sig |
| | AT | 0.94 | 20 | 0.06 | 0.01 | | | | |

Since observations are quantitative, we have used paired t-test to test efficacy. From the above table, we can observe that P-Values are less than 0.05. Hence, we conclude that the effect observed is significant.

DISCUSSION

The study was aimed to provide scientific evidence for the management of *Sthaulya* with *Navaka Guggulu*. The study was carried out in 21 registered patients of *Sthaulya*. Out of which, 20 patients completed the treatment. The observation and clinical study was done on different parameters. The results have been presented with statistical analysis.

Maximum patients (23.80%) were from the age group of 26-30 years. Ageing affects the concentration and metabolism of cholesterol in the whole body.^[10] Maximum patients (85.71%) were females. It might be due to fact that most women in this study were

students and housewives and were associated with physical inactivity. It was observed that maximum patients belonged to the Hindu religion (95.23%), which reflects the dominance of Hindus in religion. There is no established relationship between community and *Sthaulya*. The present study reflected that maximum patients were married (71.42%). This may be due to their dietary changes, more sedentary lifestyle and decreased incentives to maintain after marriage.^[11] In this series, it was noted that maximum patients (85.71%) were educated. Generally, there is more awareness about *Sthaulya* in the educated classes. Patient's knowledge regarding the significance of cholesterol as a risk factor for coronary heart disease may affect adherence. Probably that the asymptomatic nature of the disease will leave patients wondering if their cholesterol level really requires

daily attention to diet, exercise and medication.^[12] This was not found in uneducated patients who did not respond seriously on the diagnosis of the disease due to lack of symptoms. Maximum (76.19%) patients were vegetarian while rests of the patients were taking the mixed type of diet. So, it can be concluded that it may be due to general religious belief of Hindus, especially in this area. Maximum number of patients 57.14% had a sound sleep and 42.86% had disturbed sleep. Disturbed sleep might be due to late night work tendency. Also, most of the patients were worried about their health condition, which causes stress due to which the patient had disturbed sleep. In the present study, it is observed that maximum patients had *Kapha-Vataj Prakriti* (61.90%). Thus, it can be interpreted that there is dominance as well as an association of *Kaphadosha* in the constitution of the patients. *Charaka* has said, if an individual with a *Kapha* predominant constitution resorts to using *Kapha* aggravating factors, it results in an instantaneous aggravation of *Kaphadosha*.^[13] Also, the strength of a *Kaphaj* disease is the dominant *dosha* which on vitiation leads to the pathogenesis of *Sthaulya*. *Kaphavataj* body type was also significantly correlated with diabetes mellitus, hypertension and dyslipidemia with highest levels of inflammatory markers.^[14] *Koshtha* determines the bowel habit of an individual. Maximum patients (57.14%) had *Madhyama Koshta* which denotes *Kapha* dominance.^[15]

The data revealed that maximum patients were having *Madhyam Sara* (66.66%). Increased *Medadhatu* present in *Sthaulya* is a result of quantitatively increased and not a qualitative increase. Hence there is a comparative depletion of all other dhatus as compared to *Medodhatu* since the nutritive portion of the food is utilized mostly for the excessive formation of *Medodhatu*.^[16] This result eventually in decreased *Sara* of an individual. In the present study, it was found that the majority of patients had *Madhyama samhanana*, *Madhyama satva* and *Madhyama satmya* (57.14%, 42.85% and 61.90% respectively).

Madhyama satva entity makes a person uncontrolled towards lifestyle and diet. *Madhyama satmya* category showed a person's attraction toward a specific pattern of *Rasa*, *Guna* etc. All these factors add to the causative framework of the *Sthaulya*. Maximum (52.38%) patients were having *Madhyama Aharashakti*. In this study, maximum patients were found with *Mandagni* and *Madhyama koshta* also. *Kapha* dominance in *Koshtha* and *Mandagni* causes *Madhyama Aharashakti* of food. In the present study, *Avara Vyayamashakti* was found in maximum patients (47.61%). *Alpavyayama* is one of the causes associated with *Sthaulya*.^[17] The study reported that a lipid-induced defect in the nitric oxide synthesis (NOS)

pathway might impair exercise capacity by reducing oxygen transport capacity.^[18] Data revealed that 42.85% of patients were having 30-35 BMI. Obese patients on average have higher BP, higher serum total cholesterol, lower HDL cholesterol, higher serum triglycerides, higher blood glucose and a higher plasma insulin level than lean persons.^[19]

Statistically, Significant result was found in symptoms like *Chalatva*, *Daurbalya*, *Swedadhikya*, *Pipasatiyoga*, *Kshudhatimatra*, *Nidradhikya*, *Snigdghata* and *Sarvakriya Asamarthata* as the value of $p < 0.05$ in each. The percentage relief in all subjective parameters is as follows- *Chalatva*- 63.89%, *Daurbalya*- 61.11%, *Swedadhikya*- 62.96%, *Pipasatiyoga*-61.29%, *Kshudhatimatra*- 62.07%, *Nidradhikya*- 62.50%, *Snigdghata*- 60.71% and *Sarvakriya Asamarthata*-62.50%. In Objective parameters statistically significant result was found.

Overall Response

Overall response of the therapy in the patients, moderate improvement was found in 5%, marked improvement in 85% and complete improvement in 10% patients.

CONCLUSION

Various *Guggulu* preparations were used for mankind since vedic period and *Navaka Guggulu* is referenced by *Chakradutta* and Ayurvedic Formulary of India for the management of *Sthaulya*. *Guggulu Shodhana* was carried out by *Dolayantra* method in the pilot study. *Dolayantra* method is found yield beneficial. Hence *Dolayantra* method was adopted for the main study. Dose of *Navaka Guggulu* was according to AFI. *Navaka Guggulu* possess *Sthaulyahara* properties and it was found efficacious against *Sthaulya* by a randomized clinical trial.

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