

Compare the effect of Nitya Virechana in obese with Normal lipidemia and obese with hyperlipidemia- A Study Protocol

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Abstract-

Background- Obesity is a medical disorder in which there is too much body fat, which can negatively impact health, shorten life expectancy, and cause more health issues. In addition, obesity and overweight have become epidemic proportions in India in the twenty-first century, impacting 5% of the populace. **Aim-** comparing the effect of Nitya Virechana in obese with normal lipidemia and Obese with hyperlipidemia. **Objectives-** to study the effect of Nitya virechana on BMI, Lipid profile and weight. **Methodology-** This comparative, interventional investigation will be carried out on 30 participants. Two groups—Group A and Group B—of subjects will be created. nitya virechana will receive the same medications for seven days. **Result-** Both groups will participate in nitya virechana. On the basis of both subjective and objective criteria, the results will be compared. **Conclusion-** will be drowned on the result.

Index Terms- Nitya virechana, Medoroga, Obese, Normal lipidemia, hyperlipidemia.

INTRODUCTION

Obesity is a situation where the ratio of muscle to fat has accumulated to such a degree that it may negatively effect health, leading to expanded and deteriorated medical disorders in the future. A further problem affecting 5% of India's population in the twenty-first century is being overweight and obese (1).

Around 2 billion adults worldwide are overweight, and of those, 650 million are considered to be affected by obesity (BMI > 30

kg/m²), according to the World Health Organization (2016). With 13% of adults 18 and older being overweight, that comes out to 39% of men and 40% of women. Somewhere between 1975 and 2016, the prevalence of heftiness increased almost considerably overall. Since the vast majority of the world's population resides in countries where obesity and overweight kill much more people than underweight, this assessment is made (2).

In Ayurveda, obesity is referred to as "Medo Roga" and is defined as the state in which an excessive amount of body fat accumulates. Stoutness results from the body developing poisonous compounds known as ama when the agni (the fire associated with the stomach) is vitiated. Large amounts of fat tissue are present in obesity. "Overweight" refers to a highly inflated estimate of body weight that includes water, fat, muscle, and bone (3). Unconventional eating patterns and exercise routines have made medoroga (overweight) a serious issue. According to Ayurveda, the etiological causes lead to a rise in Kapha-related fat (Medovridhi), which is indicative of hyperlipidemia in the blood. (4). Medoroga (overweight /fat depositions) is an independent disease dealt with by Madhavakara (5) and Bhavamishra (6), but it is a risk factor or a component of Sthoulya (obesity) and so many other diseases. The medovahastrotodushti, i.e. obliteration or occlusion with depositions, leads to Sthula (Obesity) or Atishthoola (morbid obesity) (7).

If the medoroga is stopped at the appropriate moment, there may be little risk of generative factorial development or the emergence of disease. Because a skapha and medas are interconnected, medas

build up excessively in some body areas. Sphik (Buttock region), Stan, and Udara (Abdomen) (8). Sthoulya has long been thought to be lethal in Ayurvedic literature. According to Charaka, the Sthoulya is one of the Samtarpanjanita and the eight Ashto ninditha (eight disgusting) people roga (over nourishment). The pathogenesis of Sthoulya is mostly influenced by Kapha, Vata, and Meda. Thus, in addition to weight loss and fat reduction, the therapy is based on the neutralisation of such elements (9).

The goal of the current investigation, which extends to observing "Trivrutadiksheerpaka Nitya Virechana" (10) lipolytic effect, is to regulate fat accumulations before those accumulations become obesity and give birth to its problems. One of the five eliminative processes by which the accumulated are eliminated is the virechana. Even constipated patients benefit from the current research combo. A form of virechana is nitya virechan (daily purgation) (purgation therapy). Acharya Charaka mentions that toxins can be eliminated from the body on a daily basis in little amounts whenever there are a lot of them (11,12,13).

Rational-

Because of its rising prevalence, the Medoroga (obesity) is receiving more attention worldwide. On a global scale, it is turning into a life-threatening issue. Ayurveda, an age-old tradition, has made numerous contributions to the treatment of this lifestyle condition. The accumulation of Kapha in the body, which we must eliminate through purification, is the main samprapti ghatak of medoroga.

AIM-

To study the effect of Nitya virechana in obese with normal lipidemia and obese with hyperlipidemia.

OBJECTIVES-

To study the effect of Nitya virechana on BMI, Weight and Lipid profile.

RESEARCH QUESTION –

Does Nitya virechana reduce weight, BMI and lipid profile values?

HYPOTHESIS-

Nitya virechana is reduced weight, BMI and lipid profile values.

NULL HYPOTHESIS-

Nitya virechana is not reduced weight, BMI and lipid profile values.

Trial design- Intervention, pre-post design

Study Setting- Department of Panchakarma, Mahatma Gandhi Ayurved College Hospital and Research Centre, Salod (H), Wardha.

ELIGIBILITY CRITERIA-

INCLUSION REQUIREMENTS:

1. Patients between the ages of 20 and 50.
2. Patients with an excess weight of 25 to 29.9 kg/m²
3. Will be included are both hyperlipidemia and normal lipid levels.

EXCLUSION CRITERIA-

1. Patients receiving long-term steroid therapy
3. People who have hypertension.
4. Patients who show signs of liver, heart, and kidney dysfunction.
5. People suffering from diabetes mellitus.
6. Obesity brought on by secondary factors (PCOD)

Table No. 1- METHODOLOGY-

Grouping	Group A	Group B
Sample size	15	15
Intervention	Nitya virechana	Nitya virechana
Duration	15 days	15 days
Follow up	15 days	15 days

Table No. 2-Drugs for Virechana- Composition of Trial drugs-

Sr no	Drugs	Rasa	Virya	Vipak a	Guna	Prabhav/karma
1.	Chitrak	Katu	Ushna	Katu	Laghu, ruksha, tikshna	Deepana
2.	Danti	Katu	Ushna	Katu	Guru, teekshna	Virechana
3.	Trivruta	Katu, kashaya, madhura, tikta	Ushna	Katu	Laghu, rukshana, teekshana	Virechaka
4.	Sunthi	Katu	Ushna	Madhura	Guru, rukshana, tikshna	deepana, pachana, bheda, Vatakaphaha,
5.	Maricha	Katu	Ushna	Katu	Laghu, teekshana	Kushtaghna

6.	<i>Pippali</i>	<i>Madhur</i>	<i>Sheet a</i>	<i>Madhu r</i>	<i>Laghu, snigdha, teekshna</i>	<i>Krimighna, deepana,</i>
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Criteria for discontinuing or modifying allocated interventions-

Assume that participants will watch for any side effects and problems that the medication may cause. In that scenario, they will be removed from the study, and if any negative effects are found, the lead researcher will provide them with free medication.

Follow up- 15th days

Primary Outcome-

Nitya virechana will reduce weight, BMI and Anthropometrics parameters.

Secondary Outcome:

Nitya Virechana will lower the values of the lipid profile, including serum total cholesterol, triglycerides, low-density lipoproteins (LDL), high-density lipoproteins (HDL), very low-density lipoproteins (VLDL), and the ratio of HDL to total cholesterol.

Statistical Analysis-

Using SPSS software, data will be examined using the proper statistics, including paired unpaired t-tests and ANOVA.

Time duration till following up-

The treatment duration for the subjects will be 15th days and, after that, follow-up for 15th days.

Follow-up period-15th Days

Time schedule of enrolment, interventions-

After receiving permission from the institutional ethical committee, subjects will be gathered for the study. Nitya Virechana will make interventions.

Recruitment-

Fifteen subjects in each group will be recruited by a single randomizing sampling method.

METHODS-

A literature review search, a work plan, a flowchart-style blueprint, the gathering of raw materials, the manufacture of medicine, data collecting, the observation of the treatment's effects, and statistical analysis.

Data collections methods- Randomized sampling

Subjective Parameters-

1. Dourbalyam (general weakness)
2. Swedabadha (excessive sweating)
3. Kshudhatiyoga (excessive hunger)
4. Pipasaatimatram (excessive thirst)

Objective Parameters-

1. Body Mass Index (weight in kg divided by height in meters square)
2. Lipid profile (12 hours fasting)
 - a. Total Cholesterol
 - b. High-Density Level
 - c. Low-Density Level
 - d. Very Low-Density Level
 - e. Triglycerides
3. Weight

Investigations routine:

- Complete blood count with Erythrocytes Sedimentation Rate (To exclude any infectious condition)
- Random Blood Sugar (To rule out Diabetes Mellitus)
- Lipid profile (To rule out hyperlipidemia)

Data Management-

The principal investigator will do data coding.

Statistical Method-

For objective criteria, it used paired and unpaired analysis, nonparametric analysis for subjective criteria, and ANOVA to compare two groups.

Ethics and dissemination-

The ethical committee has authorised the research idea following a critical review and presentation to SRC and IEC.

Consent or assent-

Prior to beginning the interventions, respondents will get thorough information in their native language regarding the interventions, medication preparation, and study. Patients will then be asked for written consent.

Dissemination policy-

Data will be disseminated in paper publications and monographs: authorship eligibility guidelines and any intended use of professional writers.

INFORMED CONSENT MATERIALS-

Subjects will be given all consent material in hard copies and other related documents.

There is a striking parallel between *Medoroga* and hyperlipidemia based on *Nidanas*. *Manasika*, *Beeja Doshaja*, *Aharaja*, *Viharaja*, and Both disorders have almost identical *nidanas*, especially *Santarpankaraka*. The *Samprapti* similarly proceeds in a similar manner under both circumstances. Contrarily, in the final section, *Asthayi Medodhatu* increases due to *Medo Dhatvagnimandya* since *Sthayi Meda* has not changed, which causes a rise in the flow of lipids. Nevertheless, *Sama Sthayi Medo Dhatu* increases in *Medoroga*. In any event, since they are side effects of *Medo Dhatvagni Mandya*, both may exist in a patient. *Medoroga*, a real chemical, can be distinguished from hyperlipidemia because lipid aggravation doesn't manifest clinically unless it persists or results in physiological flaws that interact with *Medoroga*. The *Ashrayashrayi Sambhandha* of the *Kapha dosha* has a strong connection to *Meda*. Similar to how vitiated *Pitta* is involved, proper *Agni* function is impaired. As evidenced by the deficient *Dhatwaagni*, which is the work of suitable *Vayu*, *Vata* plays a part in pathogenesis. *Asthayi Medo Dhatu* is transmitted by *Rasa Dhatu*, and *Meda Dhatu* directly increases in quantity as a result of *Dhatvagnimandya*. As a result, both of these *Dhatu*s exhibit a clinically significant qualitative deterioration. *Medovaha Srotas* is the main *Srotas* to be considered, which provides the site for the formation and transport of the *Asthayi Medo Dhatu* to *Sthayi Medo Dhatu*. It should also be noted that the *Medo Dhatu* requires the vehicle of *Rasa Rakta* for their transportation.

Virechana is the procedure that uses *Adhobhaga* to help eliminate the *Vikruta Dosh*a from the *Pittasthana* in the *Koshtha*. As a result, the *Shodhana* removed *Dosha* from *Udbhava Stana*, the disease's source. *NityaVirechana* is indicated anywhere there is excessively accumulated *Dosha* (14). Additionally, *Virechana* is advised anytime Vitiated *Dosh*as are gathered in *Mamsa* and *Medo Dhatu* (15). We devised *Nitya Virechana* to

address the sickness condition of *Medoroga* predominance of *Kapha Dosh*a, which is accumulated in the *Mamsa* and *Medo Dhatu*, in order to expel the *Dosh*as and clear and open *Sroto Marga*. The following medications will be administered to *Nitya Virechana*: **Chitak** – which has *Deepan karma*, **Danti**- works as *Virechaka*, **Trivrutta**- acts as *Virechaka*, **Sunthi**- has *deepana*, *pachan*, *vatakaphahar* (16) and **Bhedan**, **Marich** – has *ushna virya* and *katu vipak*, **Pippali**- has *krimighna* and *deepan*. All drugs have *Ushna Virya* and *Katu Vipak* except *Pippali*, which has *Shita Virya* and *Madhur Vipak* and all *Jala Mahabhuta Pradhana* and *Adhobhaghar*. So it will work as *Nitya virechana*, and due to expelling out the *dosh*as, it will impair *medodhatwagni* and help reduce the weight and BMI.

Strength-

Nitya virechana will work for work on reducing BMI, Weight and Lipid profile

Limitations-

Specific geographical area, convincing the patients for *Nitya virechana* for 15th days.

CONCLUSION

The conclusion will be mentioned after the deliberate and analyzing data.

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