

**“Applied study of *Dhatwagni Siddhanta* by Comparative evaluation of
Kiratatiktadi Ghanavati versus *Tryushnadi Guggulu* in management of
Medodushtijanya Vikara (in context of Dyslipidemia)”**

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ABSTRACT

Background: Dyslipidemia is a lifestyle disorder that is frequently seen. It affects people of all ages and sexes equally. A condition known as dyslipidemia is characterised by abnormally high the level of total Cholesterol, VLDL, LDL, triglycerides and HDL in blood and this disorder is brought on by an abnormal lipid and lipoprotein metabolism and carries the risk of producing a number of complications, including cardiovascular disease, diabetes, obesity, hypertension, and others. The pathophysiology and clinical manifestation of dyslipidemia and medodushtijanya vikara are very similar. kiratatiktadi ghanavati will be work for the medodushtijanya vikar. As the outcome of this study will be positive i.e, the drug has vital action in mananagement for the Dyslipidemia. **Aim :** Revalidation the concept of *Dhatwagni Siddhant* by a comparative clinical evaluation of *Kirattiktadi Ghanavati* with *Tryushnadi Guggulu* in *Medodushtijanya Vikara* (in context of Dyslipidemia). **Objectives:** To explore the concept of *Dhatwagni*, and to explain the *Medodushtijanya Vikara* in context to *Dhatwagni*. To evaluate the efficacy of *Kiratatiktadi Ghanavati* in the *Medodushtijanya Vikara* through the correction of *Dhatwagni*. To compare the efficacy of *Kiratatiktadi Ghanavati* and *Tryushnadi Guggulu* in the *Medodushtijanya Vikara* through the correction of *Dhatwagni*. **Methodology:**

It is double arm randomized standard control single blind superiority clinical study. A total of 60 patients will be randomized into two groups at random (Every group contain 30). In Group A, *Tryushnadi Guggulu 2 vati* (500 mg of each) once a day, before meal with *koshna jala* will be given for 30 days and Group B will be given *Kirattiktadi Ghanavati 2 vati* (500 mg of each) once a day, before meal with *koshna jala* will be given for 30 days. Assesment will be done on 15th and 30th day. **Results:** Result will be declear on the basis of effect of *Kirattiktadi Ghanavati* with lipid profile test. **Conclusion:** This trial may provide evidence on the efficacy of *Kirattiktadi Ghanavati* in Dyslipidemia.

Keywords: Dyslipidemia, *medodushti janya vikara*, *Kirattiktadi Ghanavati*, *Tryushnadi Guggulu*, lipid profile test.

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INTRODUCTION:

Agni plays a significant role in life. *Agni's* dwindling poses a serious threat to survival. *Agni's* proper operation promotes longevity¹. The condition of *Agni* in the body affects a variety of bodily functions, including the maintenance of life, appearance, strength, health, sustenance, *Ojas*, *Teja* (energy), and *prana* (living energy)². *Agni's* key job is to digest food and change it into a state that is compatible with biological systems. The waste portion of the meal (*kitta bhaga*) is produced by *Agni* together with the essence or beneficial component (*anna rasa*). *Bhutagni* and *Dhatwagni* continue to circulate the food's essence as it is being processed.³ Where the *Agni* is 13 types according to their locations and functions of transformation at different levels of digestion and metabolism. Though each and every *Agni* has its own importance, *Dehagni* or *Jatharagni* is the important one as all other *Agni's* are depended upon *Jathragni* as said in *Charak Samhita*.⁴ Which means, fractions of *Grahanisthita Kayagni*, are distributed to *Dhatu*s. As per this *Siddhanta* depletion of *Medodhatvagni* produces *Ama* which leads to improper *Medodhatu Vriddhi*⁵. A condition of disrupted lipid metabolism called dyslipidemia involves abnormalities in some or all of the blood's lipoproteins.⁶ The ICMR-

INDIAN study found that hypercholesterolemia was common (13.9%), Hypertriglyceridemia was common (29.5%), low High Density Lipoprotein -C was common (72.3%), and high Low Density Lipoprotein -C levels were common (11.8%).⁷ While VLDL shows an association with early atherosclerosis, Coronary Heart Disease (CHD) level is most linked to LDL cholesterol.⁸ According to *Acharya Charaka*, In *Vishama Jwara Chikitsa*, *Kiratatikta*, *Guduchi*, *Raktachandana*, *Shunthi* are mentioned for cure of *Medashrita Jwara*. These drug acts on *Medovaha Strotasa* and remove obstruction by doing *Pachana* of *Medadhatu* in *Medashrita jwara*. Thus, by applying *Dhatwagni Siddhanta*, this drug may acts on *Medavaha Strotasa* and may cure *Medodushti*⁹.

Why *Kirattiktadi Ghanavati*?

किराततिक्तममृता चन्दनं विश्वभेषजम् | गुडूच्यामलकं मुस्तमर्धश्लोकसमापनाः|| (cha.chi 3/202)

According to *Acharya Charaka*, In *Vishama Jwara Chikitsa*, *Kiratatikta*, *Guduchi*, *Raktachandana*, *Shunthi* are mentioned for cure of *Medashrita Jwara*. These drug acts on *Medovaha Strotasa* and remove obstruction by doing *Pachana* of *Medadhatu* in *Medashrita jwara*. Thus, by applying *Dhatwagni Siddhanta*, this drug may acts on *Medavaha Strotasa* and may cure *Medodushti*¹⁰.

Need of The Study:

In regular practice, dyslipidemia is a lifestyle disorder that is frequently seen. It affects people of all ages and sexes equally. One of the main factors contributing to cardiovascular and cerebral vascular disorders is Dyslipidemia. In both industrialised and developing nations, Cardio Vascular Disease (CVDs) constitute the main cause of illness and mortality¹¹.

Content of *Kiratatiktadi Ghanavati* are *Katu*, *Tikta Rasatmaka* and *Laghu* in nature thus act on *Medodhatu* by correcting *Medodhatwagni*. So, it can be used for *Medodushti* (Dyslipidemia). Till today many works has been done on Dyslipidemia and other drugs acting on the *Medodusthijanya Vikara*. Effect of the *Tryushnadi Guggulu* also has been studied in Dyslipidemia. Till today, no clinical trial has been found which act on *Medodhatwagni* by effect of *Kirattiktadi Ghanavati* in dyslipidemia, so there is need of exploration of this drug.

Research Question:

1. Whether the concept of *Dhatwagni* is applicable in management of *Medodustijanya Vikara* (in context to Dyslipidemia)?

2. Whether *Kiratatiktadi Ghanavati* is more efficacious than *Tryushnadi Guggulu* in management of *Medodustijanya Vikara* (in context to Dyslipidemia)?

Hypothesis:

Research Hypothesis: *Kiratatiktadi Ghanavati* is more effective than *Tryushnadi Guggulu* in management of *Medodustijanya Vikara* (Dyslipidemia) in context to *Dhatwagni*.

Null Hypothesis: *Kiratatiktadi Ghanavati* is not effective than *Tryushnadi Guggulu* in management of *Medodustijanya Vikara* (Dyslipidemia) in context to *Dhatwagni*.

PICO MODEL

| | | |
|---|--------------|-------------------------------------|
| 1 | Population | Diagnosed case of Dyslipidemia N=60 |
| 2 | Intervention | <i>Kirattiktadi Ghanavati</i> |
| 3 | Control | <i>Tryushnadi Guggulu</i> |
| 4 | Outcome | Effect on lipid profile |

AIM AND OBJECTIVES:

Aim: Revalidation the concept of *Dhatwagni Siddhant* by a comparative clinical evaluation of *Kirattiktadi Ghanavati* with *Tryushnadi Guggulu* in *Medodushtijanya Vikara* (in context of Dyslipidemia).

Objectives:

- 1 To explore the concept of *Dhatwagni*, and to explain the *Medodushtijanya Vikara* in context to *Dhatwagni*.
- 2 To evaluate efficacy of *Kiratatiktadi Ghanavati* in the *Medodushtijanya Vikara* through the correction of *Dhatwagni*.
- 3 To evaluate efficacy of *Tryushnadi Guggulu* in the *Medodushtijanya Vikara* through the correction of *Dhatwagni*.
- 4 To compare the efficacy of *Kiratatiktadi Ghanavati* and *Tryushnadi Guggulu* in the *Medodushtijanya Vikara* through the correction of *Dhatwagni*.

RESEARCH GAP ANALYSIS:

| S.N. | Title and year of publication | Author | Finding of study | Remark of Scholar |
|------|---|--|---|---|
| 1. | Concept of <i>Medo Dhatu</i> : an ayurvedic prespective, 2015 | Naresh Kumar Kumawat | <i>Dhatwagni</i> especially <i>Medo Dhatwagni</i> is impaired resulting of the homologues nutrients present in <i>Poshaka Medo Dhatu</i> will be in excess in circulation and ultimately develops hyperlipidemia, <i>Medoroga</i> . | Clinical assessment of <i>Medo dhatwagni</i> is not done. |
| 2. | Concept of <i>Agni</i> and its clinical assessment – a brief review, 2019 | Dr. Suhas D. Naidu and 2 Dr. Lalitkumar V. Vithalani | we hereby conclude that one should understand the concept of <i>Agni</i> and care should be taken for proper functioning of <i>Agni</i> as it is the one which is responsible for health of an individual. | Assesment of the <i>Medodhatwagni</i> is not done. |
| 3. | Study of the effect of <i>Yavavati</i> in the management of Dyslipidemia, 2019 | Tejas Laxman kakade | <i>Yavavati</i> is safe, cost effective and easily available hence it can be used in the management of Dyslipidemia | Efficacy of <i>lekha</i> <i>Dravya</i> seen. Effect of <i>Dhatwagni Siddhant</i> is not seen. |
| 4. | A comparative clinical study to evaluate the effectiveness of <i>Tryushsanadhi Guggulu</i> and <i>Navaka Guggulu</i> in Dyslipidemia. | Merin Jose, Ravindr a Bhat K, Waheeda banu | <i>Tryushanahi Guggulu</i> and <i>Navaka Guggulu</i> mentioned in the <i>Sthoulyadhikara</i> has these properties also. <i>Navaka Guggulu</i> is a well-known drug and hence it is taken as a trial drug to compare with <i>Tryushanadhi Guggulu</i> which is having almost similar drugs in its combination. | Assesment of the <i>Medodhatwagni</i> is not done. |

There are many studies were done on Dyslipidemia by using *Shamana Chikitsa* and very few research work on individual concept of *Dhatwagni* but no study on the concept of *Dhatwagni* and applied study on management of ***Medodushtijanya Vikara (in context to Dyslipidemia)*** is noted till date. Data regarding *Kiratatiktadi Ghanavati* is not available to correct *Dhatwagni* which may be beneficial for the management of Dyslipidemia and other *Medodushtijanya Vikara*. This treatment may improve *Dhatwagni* which shows improvement in lipid profile. Till date no study found on *Medodushti*.

MATERIAL AND METHODS:

Source of Data: Patients will be recruited from the O.P.D. and IPD of the *Panchakarma & Kayachikitsa* of Mahatma Gandhi Ayurveda College, Hospital and Research Centre, Wardha, and from peripheral camps.

Sample size (Including sample size calculation):

Total Sample size: 60

Group(A): Standard Group (30)

Group (B): Intervention group

Sampling Procedure: Randomization computer generated table.

Type of Study: Interventional study

Study design: Randomized standard control single blind superiority clinical study.

Grouping & Posology:

| | Group A | Group B |
|-----------------------------|--------------------------------------|--------------------------------------|
| Name of drug | <i>Tryushnadi Guggulu</i> | <i>Kiratatiktadi Ghanavati</i> |
| Dose | 2 Vati OD (500 mg of each) | 2 Vati OD (500 mg of each) |
| Anupana | <i>Koshna Jala</i> (Luke warm water) | <i>Koshna Jala</i> (Luke warm water) |
| Aushadha sevana kala | <i>Apana kala</i> (Before meal) | <i>Apana kala</i> (Before meal) |
| Duration | 30 days | 30 days |
| Sample Size | 30 | 30 |

Study Duration: 2 year

Drug Collection / Authentication- The raw material will be procured from reliable source and drugs will be identified and authenticated by the Department of *Dravyaguna* and *Rasashashtra* of MGACH&RC Salod, Wardha.

Case Definition: Patient with classical symptoms of Dyslipidemia on the basis of Lipid profile will be selected for the study.

Data Collection tools and process:

Inclusion criteria:

- Patients willing for written informed consent to participate in the study.
- Newly diagnosed patient of the dyslipidemia (Diagnosed within 1 year).
- Age between 20-60 years of either gender.
- Patient with controlled hypertension (systolic not more than 140 mmHg and diastolic not more than 90 mmHg)
- Patient with controlled type II diabetes (fasting below 130mg/dl, pp- below 180 mg/dl)
- Subjects fulfilling the following objective criteria of Dyslipidemia-

Exclusion criteria:

- Patients of age group below 20 yrs. and above 60 yrs.
- Other systemic disorder- Cardiovascular disorder, Atherosclerosis and renal disorders etc.
- During pregnancy and lactation period in women.
- Chronic patients of Dyslipidemia.

METHODOLOGY:

Place of study: The Patients of Dyslipidemia will be selected from OPD and IPD of Mahatma Gandhi Ayurveda College, Hospital & Research Center, Salod (H) and from specialized peripheral camps.

Composition of drug: *Kiratatiktadi* (*Kiratatikta* ,*Guduchi* ,*Raktachandan* , ,*Shunthi*) *Ghanavati*.

Table No.1 Ghatak dravya of *Kiratatiktadi Ghanavati*

| Sr.No. | Ingredients | Botanical Name | Part use | Quantity |
|--------|-----------------------|-------------------------------|-------------------|----------|
| 1 | <i>Kiratatikta</i> | <i>Swartia chiraita</i> | <i>Root</i> | 1 part |
| 2 | <i>Guduchi</i> | <i>Tinospora cardifolia</i> | <i>Stem</i> | 1 part |
| 3 | <i>Rakta Chandana</i> | <i>Pterocarpus Santalinus</i> | <i>Heart wood</i> | 1 part |
| 4 | <i>Shunthi</i> | <i>Zinziber officinalis</i> | <i>Rhiozme</i> | 1 part |

Details of Drug Preparation:

- **Preparation of *Kiratatiktadi ghanvati* ^[12]:**

All the ingredients are collected, cleaned and crushed in *Khalva Yantra*.



Then, the drug is later taken in a bigger vessel along with 8 parts of water.



Then, the mixture is boiled over mild fire and reduced to 1/4th part.



Then, the reduced liquid is filtered through a clean cloth to another vessel.



Then, the filtrate is boiled further and brought to a thicker consistency



Then, the *Ghanavati* of desired size are prepared, dried in shade and preserved in airtight containers.

Table No.2 Ghatak dravya of *Tryushanadi Guggulu*

| Sr. No. | Ingredients | Botanical Name | Part Used | Quantity |
|---------|----------------|------------------------------|-----------|----------|
| 1 | <i>Shunthi</i> | <i>Zinziber o fficinalis</i> | Rhizome | 1 Part |

| | | | | |
|---|--------------|---------------------------------|-----------|---------|
| 2 | Marich | <i>Piper nigrum</i> | Fruit | 1 part |
| 3 | Pippali | <i>Piper longum</i> Linn. | Fruit | 1 part |
| 4 | Chitrak | <i>Plumbago zeylanica</i> .Linn | Root bark | 1 part |
| 5 | Musta | <i>Cyperus rotundus</i> Linn. | Rhizome | 1 part |
| 6 | Vidanga | <i>Embelia ribes</i> | Fruit | 1 part |
| 7 | Vacha | <i>Acorus calamus</i> Linn. | Rhizome | 1 part |
| 8 | Shudh Guggul | <i>Commiphora mukul</i> | Gum resin | 7 parts |

Details of preparation of *Tryushanadi Guggulu*^[13]:

Shuddha Guggulu taken and little water boiled over *Mandagni* till it dissolve completely



Fine powder of *Tryushnadi churna* are added in *Guggulu kwatha* and mixed thoroughly



All these drugs pounded in *khalva yantra* by adding little quantity of Ghee to make a soft paste



Tablets are made and store in a airtight container after drying.

ASSESSMENT CRITERIA:

Subjective criteria:

- *Dhatwagni* assessment criteria. (Validated questionnaire-content validity only)

| Sr.no | <i>Jarnashakti Parikshana</i> ¹⁴ | Present | Absent |
|-------|---|---------|--------|
| 1 | <i>Deha Laghavta</i> (lightness of the body) | | |
| 2 | <i>Anna Shraddha</i> (liking towards food intake) | | |
| 3 | <i>Kshudha</i> (Appetite) | | |
| 4 | <i>Klama Pariagamana</i> (exhaustiveness in the body) | | |
| 5 | <i>Vegotsarga</i> (timings of urination & defecation) | | |

| Sr. No. | <i>Medodusthti lakshana</i> ¹⁵ | Present | Absent |
|---------|---|---------|--------|
| 1 | <i>Udara Parshwa vridhhi</i> (Belly fat) | | |
| 2 | <i>Snigdhanga</i> (unctuous body parts) | | |

| | | | |
|---|--|--|--|
| 3 | <i>Medurmansa prarthana (Desire of having mamsa)</i> | | |
| 4 | <i>Katishoola (Low back pain)</i> | | |
| 5 | <i>Udara tanutva (thinning of the abdomen)</i> | | |
| 6 | <i>Ayasa (Fatigue)</i> | | |

Objective Criteria:**Criteria [ATP-III (NCEP) criteria]¹⁶**

| Sr.No. | Type of Cholesterol | Range |
|--------|-----------------------|-----------------|
| 1 | Serum Triglycerides | 150-499mg/dl |
| 2 | Serum Cholesterol | 200 ≥ mg/dl |
| 3 | Serum LDL Cholesterol | 130 – 189 mg/dl |
| 4 | Serum HDL Cholesterol | < 40 mg/dl |

ANALYSIS PLAN

Drug Analysis: Raw medications would be obtained from trustworthy source, identified and authenticated by the Department of *Dravyaguna*, Mahatma Gandhi Ayurveda College, Hospital & Research Centre, Salod (H), Wardha.

Statistical analysis: Wilcoxon test is a statistical test that is used to compare two groups of people. To analyse the data with objective criteria, Paired and Unpaired t tests will be utilised. To analyse the data using subjective criteria, McNamara's test will be employed.

Followed period: 0-day, 15 day and follow up 30 days

Time schedule of enrolment, interventions: orally

Method: Literature study, work strategy, flow chart-style blueprint, preparation of the medication, data collecting, treatment, and effects will all be examined, along with the optimum method of administration and statistical analysis.

Data collection Method: Randomized Sampling.

Data management: The principal investigator will code the data.

Statistical Method: According to objective criteria, both paired and unpaired. For subjective criterion, non-parametric.

Follow up: Patients will be followed up on 15th - day and 30th days during the period of treatment.

Primary Outcome: We will see the impact of *Kiratatiktadi Ghanavati* on *Medodushtijanya vikara* (Dyslipidemia).

Secondary Outcome: We will see the conceptually and practically establishment of *Dhatwagni Siddhant* from above the statement.

DISCUSSION:

Dyslipidemia is a lifestyle disorder that is frequently seen. The main causes of Dyslipidemia are irregular eating habits, a sedentary lifestyle, a family history of Dyslipidemia, regular alcohol usage, smoking, and stress¹⁷. All of these *Hetus* aggravate the *Kapha* and *Meda*, resulting in *Strotoavrodha*. The regular movement of *Vayu* is obstructed due to *Strotoavrodha*. This impeded *Vayu* enters the *Koshtha*, resulting in *Jatharagni Sandhukshana* (increased ability for digestion), which stimulates the early digestion of ingested food, resulting in insatiable appetite and a desire for huge amounts of food. Due to *Strotoavrodha*, *Vayu* and *kapha* goes to *koshtha* and make *jatharagni Sandhukshana* which then leads to *Medokshaya* and similarly when *Kapha* is increased that leads to *Medovridhi*. Dyslipidemia is a type of *Kaphavikara* that may especially take the form of *Abaddha Meda* in *Medodushti*. *Abaddha Meda*-representing the fat which circulate freely in the form of plasma lipid.¹⁸ *Ghanavati* is widely used dosage form, exact dose can be delivered to the patient, easy for administration, palatable, easy for transport and packaging. This way tablets have more advantage over other dosage form. Ingredients used in *kiratatiktadi ghanavati* are the same as mentioned in *Charak Samhita*. According to *Acharya Charaka*, In *Vishama Jwara Chikitsa*, *Kiratatikta*, *Guduchi*, *Raktachandana*, *Shunthi* are mentioned for cure of *Medashrita Jwara*. These drug acts on *Medovaha Strotasa* and remove obstruction by doing *Pachana* of *Medadhatu* in *Medashrita jwara*. Thus, by applying *Dhatwagni Siddhanta*, this drug may acts on *Medavaha Strotasa* and may cure *Medodushti*.

Scope of implications of the proposed study: If *Kiratatiktadi Ghanavati* correct *Medodhatwagni* as result of *Medakshaya* in *Medodushti* (Dyslipidaemia) then it may also be useful in other disease arise from *Medodushti*.

Ethics and dissemination: Research ethical approval: After critical evaluation and presentation the ethical committee has approve the research topic reference No-MGACHRC/IEC/July-2022/562

Consent or assent: The written consent will be taken before starting the study from the patient. During the study the confidentiality of each patient will be properly maintained.

Strengths: kiratatiktadi ghanavati will be work for the medodushtijanya vikar. If proposed study results in the positive outcome, then it will be established new mode of management for the Dyslipidimia.

CONCLUSION:

Conclusion will be mentioned after the deliberate and analysing data.

Ethical Clearance: Taken from institutional ethics committee.

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