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# A single-arm clinical study to evaluate the efficacy of *Chirbilva Ghana Vati* in the management of Hyperlipidaemia

**Research Article**

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## Abstract

Hyperlipidaemia, characterized by elevated blood lipid levels, is a major cause of coronary heart disease and atherosclerosis. In India, dyslipidaemia affects 25-30% of urban and 15-20% of rural populations, with familial hypercholesterolemia prevalent in 1:125 to 1:450 individuals in urban areas. In Ayurveda, hyperlipidaemia is linked to conditions like *Rasagata Sneha Vriddhi* (increase in fat in the circulation), *Rasa Raktagata Sneha Vriddhi* (increase in fat in the blood), and *Medovriddhi* (increase in fat tissue), attributed to sedentary lifestyles and *Kapha*-aggravating diets. This leads to excess *Medas* (fat) that block nutrient channels, a condition similar to modern hyperlipidaemia. Objective: The study aimed to reduce lipid accumulation through *Rukshana Chikitsa* (drying therapy). *Chirbilva,* known for its *Ruksha* (dry) and *Laghu* (light) properties and *Kapha-Medohara* (fat-reducing) action, was selected for managing *Kapha*-dominant lipid disorders such as hyperlipidaemia. Material and methods: The study, conducted at Dr. D.Y. Patil College of Ayurveda and Research Centre, Pune, the study included 30 patients with hyperlipidaemia. *Chirbilva Ghana Vati* was administered as per classical Ayurvedic guidelines. Lipid profile scores were evaluated pre- and post-treatment using criteria based on the American Journal of Lifestyle Medicine, with statistical analysis set at $p < 0.05$. Result: *Chirbilva Ghana Vati* showed significant reductions in serum cholesterol and LDL levels, indicating moderate efficacy. However, changes in HDL and triglyceride levels were not statistically significant. Conclusion: Chirbilva Ghana Vati demonstrates moderate effectiveness in managing hyperlipidaemia. For enhanced and sustained results, longer treatment duration along with appropriate dietary and lifestyle modifications is recommended.

**Keywords:** Hyperlipidaemia, *Chirbilva Ghana Vati*, Cholesterol, *Santarpana janaya vyadhi, Aptarpana chikitsa*.

## Introduction

Hyperlipidaemia refers to elevated blood lipid levels, including hyperlipoproteinemia and hypercholesterolemia, and is a major contributor to coronary heart disease and atherosclerosis. Dyslipidaemia, the most critical risk factor for atherosclerosis, is increasingly prevalent in India, affecting 25–30% of urban and 15–20% of rural populations, though still lower than rates in high-income countries(1). Urban areas show significant increases in LDL cholesterol and triglycerides, with studies linking coronary events to elevated apolipoprotein B, total cholesterol, LDL, and non-HDL cholesterol, and low apolipoprotein A and HDL cholesterol. The prevalence of suspected familial hypercholesterolemia in urban India is estimated at 1:125 to 1:450, but awareness and treatment remain inadequate, especially for borderline high LDL, low HDL, and high triglycerides. Additionally, while cholesterol levels have risen over the past 20 years, comprehensive studies on lipid abnormalities in children are lacking. In Ayurveda, hyperlipidaemia is not directly mentioned but is correlated with conditions like *Rasagata Sneha Vriddhi*, *Rasa Raktagata Sneha Vriddhi*, *Medovriddhi*, and *Medoroga*. It is attributed to sedentary lifestyles and *Kapha*-aggravating diets, leading to excess *Medas* (fats) that obstruct nutrient channels and deprive other tissues of nourishment. This accumulation, termed *Abaddha Medovriddhi*, aligns with hyperlipidaemia in modern terms. Treatment focuses on reducing *Sneha Vriddhi* (lipid accumulation) through *Rukshana Chikitsa*, one of the six treatment modalities (*Shadvidha Upakramas*) described in the *Charaka Samhita*(2). Diseases arising from over nourishment (*Santarpana*) are managed with depletion therapies (*Aptarpana Chikitsa*) and vice versa, ensuring balance in the doshas and dhatus. In this study, *Chirbilva* was used for its *Kaphamedo Vishoshana* (Kapha and fat-reducing) and *Lekhaniya* (scraping) properties. Its *Ruksha* (dry) and *Laghu* (light) qualities make it ideal for managing *Santarpana Janya Vyadhi* (over nourishment-related disorders) like hyperlipidaemia. As per *Charaka Samhita*, *Rukshana*

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*Chikitsa* (drying therapy) is recommended for *Kapha* and *Sneha* accumulation in the *Srotas* (channels), particularly in *Marmastha Vyadhi* (vital organ disorders) such as cardiovascular diseases. Fast-food consumption, lack of exercise, irregular sleep, stress, and addictions disrupt metabolism, increasing susceptibility to disorders like hyperlipidaemia. A key risk factor for cardiovascular diseases (CVDs), metabolic syndrome, and hypertension, hyperlipidaemia often coexists with hypertension and can be managed through medications or lifestyle changes. Prolonged high insulin levels also contribute to hyperlipidaemia.

Hyperlipidaemia plays a significant role in atherosclerosis, affecting large and medium-sized arteries and leading to coronary heart disease (CHD). As CVDs remain the leading cause of death globally, rapid urbanization and associated negative lifestyle changes are major contributors to their rise.

In *Charaka Samhita*, Acharya Charaka identifies *Dhamanipratichaya* as one of the twenty *Kaphaja Nanatmaja Vikaras*, characterized by thickening or accumulation in blood vessels, akin to modern atherosclerosis. This condition arises from *Kapha Karaka Nidana* such as a sedentary lifestyle, high-calorie diet, and lack of physical activity, leading to *Kapha Dosha* and *Medo Dhatu* imbalance. Impaired fat metabolism (*Medodhatvagnimandya*) and *Kapha-Meda Dushti* result in excessive accumulation in *Rasa- and Raktavaha Srotas*, obstructing *Vata* and *Rakta* flow. This pathology aligns with dyslipidaemia in modern medicine.

Considering the significant role of hyperlipidaemia in life-threatening diseases and its partial comprehension in Ayurveda, this study, *"A Single-Arm Clinical Study to Evaluate the Efficacy of Chirbilva Ghanvati in the Management of Hyperlipidemia"*, was planned and conducted.

## Materials and methodology

### Study design

A single-arm clinical study.

### Study Setting

Conceptual study, pharmaceutical study and clinical study followed by statistical tests.

### Study population

The clinical study will be performed on a group of 30 patients from the OPD and IPD of Dr. D.Y. Patil College of Ayurved and Research Centre, Pimpri, Pune.

### Source of Material

Participants of the study were recruited from the Kayachikitsa Outpatient Department of the Dr. D.Y. Patil College of Ayurved and Research Centre located in Pimpri, Pune. The required raw materials for the *Chirbilva Ghana Vati* formulation were obtained from the pharmacy of Vijaya Ayurvedic Pharmacy, Kerala. The *Chirbilva Ghana Vati* was manufactured within the Rasashala (pharmaceutical laboratory) of the Dr. D.Y. Patil Ayurved College, Hospital and Research Centre situated in Pune.

### Selection Criteria

The inclusion criteria for the study were as follows: patients aged between 20 to 70 years were considered eligible. Participants were required to have serum cholesterol levels greater than 200 mg/dL, serum triglycerides exceeding 150 mg/dL, serum HDL levels below 40 mg/dL, and serum LDL levels above 130 mg/dL. Patients of either gender diagnosed with hyperlipidaemia were included. Both newly diagnosed hyperlipidaemic patients and those with a known history of hyperlipidaemia who were not currently receiving any treatment were eligible for inclusion in the study.

The exclusion criteria comprised pregnant women and lactating mothers, patients suffering from psychological disorders such as anxiety and depression, and individuals with severe renal, hepatic, or coronary heart disease.

Withdrawal criteria were clearly defined: patients could be withdrawn from the study or treatment under the following circumstances—(a) if they developed any serious adverse effects, (b) in case of lack of response to treatment along with worsening of symptoms, thereby requiring referral to another medical specialist, or (c) refusal by the patient to continue with the treatment at any point during the study.

### Criteria for assessment

The range for the lipid profile was established based on guidelines from American Journal of Lifestyle Medicine, and the scoring pattern was set accordingly(3). Patients were selected based on their initial lipid profile and lipid profile after intervention with the Ayurvedic formulation *Chirbilva Ghana Vati.* The inclusion criteria included patients of any weight, with well-defined lipid profile thresholds is shown in the table no. 1.

**Table 1: Diagnostic Criteria for Dyslipidaemia Based on Lipid Profile Values**

| Lipid Profile | Level |
|---|---|
| Serum Cholesterol | > 200 mg/dL |
| Serum Triglycerides | > 150 mg/dL |
| Serum HDL | < 40 mg/dl |
| Serum LDL | > 130 mg/dl |

### Assessment Criteria for Evaluating Therapeutic Outcome

The overall therapeutic efficacy was evaluated primarily on the basis of objective parameters reflecting the *Roga Bala* (severity of the disease) in hyperlipidaemia. As hyperlipidaemia is largely an asymptomatic metabolic disorder, diagnosis and assessment rely solely on biochemical analysis, specifically the lipid profile.

To quantify outcomes, the lipid profile was assigned a cumulative score of 80, with equal weightage (20 points each) allotted to the four components i.e., Serum Cholesterol, Serum Triglycerides, Serum High-Density Lipoprotein, Serum Low-Density Lipoprotein. Scoring was carried out in accordance with the lipid

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threshold values as per American Journal of Lifestyle Medicine (4).

### Scoring Criteria

The scoring criteria for lipid profile values are presented in Table 2.

**Table 2: Evaluation and Scoring of Lipid Profile Values**

| **Serum Cholesterol** | |
|---|---|
| **Level** | **Grading** |
| >240 mg/dl | 0 |
| 200-239 mg/dl | 10 |
| <200 mg/dl | 20 |
| **Serum Triglycerides** | |
| **Level** | **Grading** |
| 500 mg/dl | 0 |
| 200-499 mg/dl | 5 |
| 150-199 mg/dl | 10 |
| <150 mg/dl | 20 |
| **Serum High-Density Lipoprotein** | |
| **Level** | **Grading** |
| <40 mg/dl | 0 |
| 40-60 mg/dl | 10 |
| 60 mg/dl | 20 |
| **Serum Low-Density Lipoprotein** | |
| **Level** | **Grading** |
| 190 mg/ dl | 0 |
| 160-189 mg/dl | 5 |
| 130-159 mg/dl | 10 |
| <130 mg/dl | 20 |

The overall percentage improvement was then derived from the cumulative score obtained before and after treatment.

### Ethical consideration

The study was approved by the institutional ethics committees of the participating centres prior to commencement. (IEC No- DYPCARC/IEC/542/2022). Prior to recruiting participants, the trial was registered with the Clinical Trials Registry of India, CTRI/ 2023/03/051185. In reporting the study findings, the STROBE guidelines have been adhered to.

### Source and authentication of the drugs

This study evaluates the therapeutic efficacy of *Chirbilva Ghana Vati*, a compound preparation that draws upon the "*Lekhaniya Mahakashaya*" described in the Ayurvedic text "*Charak Samhita*" (5) and the "*Salsaradi gana*" mentioned in the *Sushrut Samhita (6)*. The raw materials for the *Chirbilva Ghana Vati* formulation that is *Chirbilva (Holoptelia integrifolia)* were procured from the pharmacy of Vijaya Ayurvedic Pharmacy, Kerala.

### Preparation of *Chirbilva Ghana Vati*

*Chirbilva* was finely powdered and mixed with sixteen times its volume of water in a stainless-steel vessel. The mixture was gently heated and reduced to one-fourth of its original volume with continuous stirring to prevent scorching. The resulting *Kwatha* (decoction) was filtered through a fine cotton cloth to obtain the potent liquid extract (7). This decoction was then boiled again on a slow fire until a semi-solid consistency (*Ghana*) was achieved as the water evaporated (8)(9). The prepared *Ghana* was dried in a hot air dryer, passed through a no. 16 sieve, further dried, and sieved again through a no. 20 sieve. For tablet formation, 7% starch was added as a binder and 2% talc as a lubricant. The final granules were compressed into 500 mg tablets using a 16 STN single rotor punch tablet press.

### Intervention

The intervention protocol involved administering 500mg *Chirbilva Ghana Vati*, 2 Tablet twice daily before meals, with *anupana* (adjuvant taken with a medicine ) of luke warm water. for a duration of 1 month. This formulation was specially prepared at the pharmacy of Dr. D.Y. Patil College of Ayurved and Research Center, Pune, to ensure quality and adherence to Ayurvedic standards.

### Grouping

A total of 40 patients from the OPD were screened, 36 of whom met the inclusion criteria and were enrolled in the study for drug administration. However, 6 patients discontinued the intervention because of irregular follow-up and a lack of interest. Ultimately, 30 patients successfully completed the study.

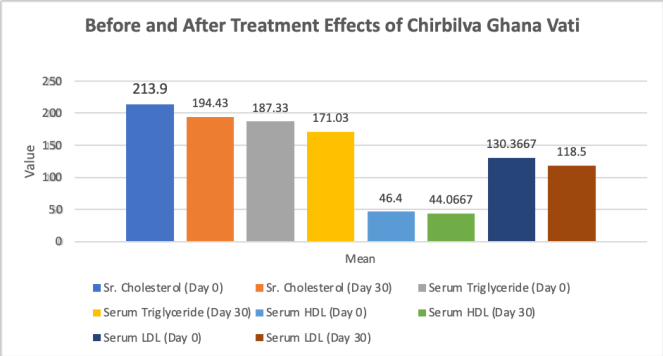
## Results

To understand how *Chirabilva Ghana Vati* affected serum cholesterol Levels, the research team used both visual representations of the data (graphs and tables) and a statistical test called a dependent t-test. This two-pronged approach helped determine how effective *Chirabilva Ghana Vati* was in managing the lipid levels in the patient group. Lipid profile variations pre- and post-treatment are illustrated in Table 3 and Graph 1.

**Table 3: Before and After treatment effect of *Chirbilva Ghana Vati***

| **Lipid Profile** | **Mean** | **SD** | **Mean Difference** | **SD Difference** | **P value** |
|---|---|---|---|---|---|
| Sr. Cholesterol (Day 0) | 213.90 | 35.41 | 19.47 | -5.5 | 0.001 |
| Sr. Cholesterol (Day 30) | 194.43 | 40.91 | | | |
| Serum Triglyceride (Day 0) | 187.33 | 99.559 | 16.3 | 27.587 | 0.202 |
| Serum Triglyceride (Day 30) | 171.03 | 71.972 | | | |
| Serum HDL (Day 0) | 46.4000 | 7.89413 | 2.33 | -1.33 | 0.131 |
| Serum HDL (Day 30) | 44.0667 | 9.23238 | | | |
| Serum LDL (Day 0) | 130.3667 | 43.10171 | 11.86 | 1.426 | 0.026 |
| Serum LDL (Day 30) | 118.5000 | 41.67588 | | | |

**Graph 1: Graphical Representation of Before and After Treatment Effects of *Chirbilva Ghana Vati***



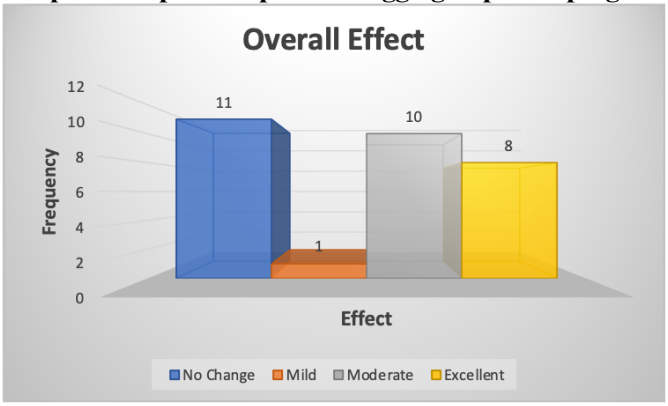

### The therapy's net impact

This study examines the efficacy of *Chirbilva Ghana Vati* in managing Hyperlipidaemia. The table below presents the individual results for the 30 patients enrolled, detailing their experience of mild, moderate, and complete relief. The overall effect of *Chirbilva Ghana Vati* in hyperlipidemia is shown below in Table No. 4 and Graph No. 2, depicting the comparative changes in lipid profile parameters before and after the intervention.

**Table 4 : Percentage-based analysis of overall patient improvement**

| Overall Effect | Frequency | Percentage Effect |
|---|---|---|
| No Change | 11 | 36.7 |
| Mild | 1 | 3.3 |
| Moderate | 10 | 33.3 |
| Excellent | 8 | 26.7 |
| Total | 30 | 100 |

**Graph 2: Graphical depiction of aggregate patient progress**




## Discussion

In today's fast-paced world, the rise of hyperlipidaemia mirrors the modern challenges of dietary habits and lifestyle choices. The increasing prevalence of this metabolic disorder is a direct consequence of the widespread consumption of unhealthy foods and sedentary living. Hyperlipidaemia, characterized by elevated levels of cholesterol and triglycerides in the blood, is no longer just a condition of the aging population but affects individuals across various age groups, making it a pressing public health concern. As the global community grapples with this epidemic, it is essential to explore both conventional and traditional approaches to understanding and managing hyperlipidaemia.

Present-day food habits and lifestyle choices play a significant role in the increasing prevalence of hyperlipidaemia. Dietary patterns observed in patients with hyperlipidaemia often include a high intake of saturated and trans fats from red meat, full-fat dairy, and processed foods, contributing to elevated LDL cholesterol levels. Excessive consumption of refined sugars and simple carbohydrates, such as sugary beverages, pastries, and white bread, has been linked to insulin resistance and higher triglyceride levels. Additionally, a low intake of dietary fiber from fruits, vegetables, and whole grains further exacerbates cholesterol imbalances, hindering lipid metabolism.

A sedentary lifestyle is another major contributing factor. Prolonged inactivity due to desk jobs and increased screen time, coupled with insufficient physical exercise, has been directly associated with weight gain, obesity, and disrupted lipid metabolism. Chronic stress and sleep deprivation compound the issue by causing hormonal imbalances, leading to unhealthy eating patterns and an increased risk of hyperlipidaemia. Furthermore, excessive alcohol consumption elevates triglyceride levels and contributes to fatty liver disease, while smoking reduces HDL cholesterol and heightens the risk of atherosclerosis, worsening lipid profiles.

From an Ayurvedic perspective, hyperlipidaemia aligns with *Medoroga* (disorder of fat metabolism), linked to imbalances in *Medas Dhatu* (fat tissue) and *Kapha dosha*. Poor dietary habits, lack of exercise, and high stress contribute to *Agnimandya* (weakened digestive fire), leading to the accumulation of *Ama* (toxins) and disturbed lipid metabolism. Foods that are heavy, oily, and sweet aggravate *Kapha* and *Meda Dushti* (vitiation of fat tissue), while *Laghu* (light) and *Ruksha* (dry) foods, along with bitter, astringent, and pungent tastes, help balance *Kapha* and reduce *Medas Dhatu*. Regular physical activity, stress management techniques such as *yoga* and *pranayama*, and detoxification therapies like *Panchakarma* (fivefold detoxification therapies) have shown significant benefits in managing hyperlipidaemia by balancing doshas (biological energies) and eliminating *Ama*.

Ayurveda, explains lipid metabolism through the concept of *Medo Dhatu* (fat tissue), categorized into *Upadana Medo Dhatu* (precursor adipose tissue), *Asthayi Medo Dhatu* (circulating lipids), and *Sthayi Medo Dhatu* (adipose tissue storage). Lipids, being predominantly *Prithvi* (earth element) and *Apa Mahabhuta* (water element) in structure and *Teja Mahabhuta* (fire element) in function, share similarities with *Kapha* and *Pitta* doshas. The role of *Agni* (digestive fire), particularly *Jatharagni* (digestive fire at the stomach level), *Bhutagni* (metabolic fire of the five basic elements), and *Dhatvagni* (metabolic fire at the tissue level), is critical in maintaining lipid metabolism. Impairment of these metabolic fires leads to the accumulation of *Ama Medo Dhatu* (toxins in fat tissue), resulting in tissue dysfunction and hyperlipidemia (5).

Ama plays a pivotal role in hyperlipidaemia by obstructing channels (*Srotorodha*) and disrupting *doshic* balance, leading to metabolic disturbances, fatigue, and cardiovascular issues. Its sticky nature adheres to arterial walls, trapping lipoproteins and contributing to vessel blockages. Ayurveda emphasizes the importance of rekindling *Jatharagni* to clear *Ama* and restore balance, with herbal formulations like *Chirbilva Ghanavati* offering a holistic approach to managing hyperlipidaemia. By promoting proper digestion and addressing the root cause, Ayurveda provides a sustainable and side-effect-free alternative to conventional treatments.

Synthetic drugs are increasingly linked to numerous side effects, whereas herbal medicines are recognized for their lipid-lowering and antioxidant properties, typically without significant adverse effects. Recently, herbal hypolipidemic agents have gained prominence as a promising alternative to address the limitations posed by synthetic medications(10). Modern treatments, such as statins and fibrates, are well-established for managing hyperlipidaemia. However, prolonged use of these drugs often leads to side effects, including diarrhoea, dizziness, constipation, flatulence, stomach discomfort, and muscle pain, while requiring lifelong adherence(11).

**The mechanism of action of *Chirbilva Ghana Vati***

*Chirbilva Ghana Vati* addresses hyperlipidaemia by targeting the root causes outlined in Ayurveda, including excess *Kapha* due to improper diet, lifestyle, and psychological factors. The disruption of *Jatharagni* (digestive fire) leads to the accumulation of *Aama* (toxins), which weakens *Medodhatvagni* (metabolic fire for fat metabolism) and results in hyperlipidemia (12). *Chirbilva Ghanavati* combats this through its *Tikta* (bitter), *Katu* (pungent), and *Kashaya* (astringent) *Rasas*, along with its *Katu Vipaka* (pungent post-digestive effect) and *Laghu* (light), *Ruksha* (dry) *Gunas* (13). These qualities help in *Medopashoshana* (drying up fat), *Medovishoshana* (expelling fat), and *Lekhana Karma* (scraping action), which purify the body's channels (*Strotansi Vivrnoti*) and restore balance to the *Medovaha Srotas* (fat metabolism channels). Its synergistic effects strengthen the digestive fire and improve fat metabolism, aiding in the management of hyperlipidemia. *Chirbilva Ghanavati* is referenced in the "*Lekhaniya Mahakashaya*" of Charak Samhita and "*Salsaradi Gana*" of Sushrut Samhita.

**Impact of *Chirbilva Ghana Vati* on Lipid Profiles**

The administration of *Chirbilva Ghana Vati* demonstrated varying levels of improvement in lipid profile parameters. Notably, a significant reduction was observed in mean serum cholesterol and LDL levels. However, changes in HDL and triglyceride levels were not statistically significant. Overall, *Chirbilva Ghana Vati* contributed to a modest enhancement of lipid profile parameters, with pronounced effects on cholesterol and LDL levels.

## Conclusion

The present clinical study demonstrated that *Chirbilva Ghana Vati* exhibits moderate yet promising efficacy in the management of hyperlipidaemia. Within just one month of administration, it led to a notable reduction in serum cholesterol and LDL levels, without eliciting any adverse effects—highlighting its safety and tolerability for long-term use. However, the formulation showed no statistically significant impact on triglyceride levels or HDL cholesterol. The findings underscore the influence of unwholesome dietary patterns—including frequent snacking, excessive intake of non-vegetarian and junk foods—combined with sedentary lifestyles, lack of physical exertion, and daytime sleep, as significant contributors to lipid imbalances. From an Ayurvedic perspective, hyperlipidemia can be effectively addressed through *Apatarpan Chikitsa* (reduction therapy), which aims to pacify aggravated doshas, eliminate metabolic toxins (*ama*), and restore physiological harmony. The pharmacological actions of *Chirbilva Ghana Vati* resonate with this therapeutic approach. While initial outcomes are encouraging, a prolonged treatment duration of 3–4 months, along with personalized dietary and lifestyle counseling, is strongly recommended to optimize therapeutic benefits. Taken together, *Chirbilva Ghana Vati* emerges as a safe, moderately effective, and integrative Ayurvedic intervention for managing hyperlipidaemia, especially when complemented by holistic lifestyle modifications.

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