

Comparative Efficacy of *Lekhan Basti* with *Ushkadi Gana* versus *Triphala Gana* as against Standard Control in Dyslipidaemia (*Medoroga*): A Research Protocol for a Randomised Controlled Trial

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ABSTRACT

Introduction: Ayurveda addresses *Medoroga* using a holistic approach, focusing on correcting imbalances and utilising cleansing therapies like medicated enema (*Basti*). *Ushakadi Gana* includes herbs with potential lipid-lowering and metabolic effects, but it faces challenges in accessibility and cost. *Triphala Gana* offers a more accessible herbal alternative. This study aims to compare the efficacy of both formulations, providing insights into their application for managing dyslipidaemia (*Medoroga*).

Need of the study: In modern medicine, Atorvastatin is the drug of choice for treating dyslipidaemia (*Medoroga*). Dyslipidaemia can be correlated with *Medoroga* in *Ayurveda*. The ingredients of *Ushakadi Gana* are not easily available for the preparation of *Basti* and do not include herbal drugs. The *Ushakadi Gana Basti* is effective, it poses challenges due to its high cost, limited accessibility, and concerns regarding its mineral content, which is contraindicated for patients with renal and

hepatic impairments. *Lekhan Basti* with *Triphala Gana* offers an alternative due to its herbal composition.

Aim: To evaluate the efficacy of *Lekhan Basti* with *Ushadi Gana* versus *Lekhan Basti* with *Triphala Gana* compared to standard control in managing dyslipidaemia (*Medoroga*).

Materials and Methods: A randomised single (assessor) blind triple-arm superiority controlled trial will be conducted at Mahatma Gandhi Ayurvedic College, Hospital and Research Centre, Salod, Wardha, Maharashtra, India, from January 2025 to March 2026. A total of 129 patients will be divided into three groups, each comprising 43 patients. Group A (n=43): *Lekhan Basti* with *Triphala Gana* for 16 days, Group B (n=43): *Lekhan Basti* with *Ushakadi Gana* for 16 days and Group C (n=43): Standard treatment with Atorvastatin (1 tablet, 10 mg) daily after food for 48 days. Therapeutic outcomes, lipid profile levels, Body Mass Index (BMI), and weight will be assessed at baseline and follow-up. Analysis of Variance (ANOVA) tests will be applied for statistical analysis, with p-value <0.05 considered significant.

Keywords: Body mass index, Cardiovascular disease, Enema, Hyperlipidaemia, *Kapha*, *Karshana basti*, Obesity, Sedentary lifestyle, Weight loss

INTRODUCTION

Dyslipidaemia (*Medoroga*) is a disorder of lipoprotein metabolism marked by high total cholesterol, elevated Low Density Lipoprotein (LDL), increased triglycerides, and low High Density Lipoprotein (HDL) levels. Contributing factors include a lack of physical activity, poor sleep, sedentary lifestyles, and stress-related behaviours. The main causes are unhealthy eating habits, such as consuming processed and junk foods, along with irregular meal times. Dyslipidaemia is increasingly common and may indicate underlying conditions like obesity, metabolic syndrome, diabetes, hypertension, and cardiovascular disease [1]. The increased cardiovascular risk associated with obesity is at least partly mediated through atherogenic dyslipidaemia, which is characterised by an increase in plasma triglycerides, high levels of LDL cholesterol, and low concentration of HDL cholesterol [2,3]. According to a study, dyslipidaemia is most prevalent in people over 30 years old (36.4%), followed by those aged 24-30 (21.1%), and is least prevalent in people aged 20-22 (10.5%) [4].

The global burden of disease analysis indicates that heart problems are currently the second leading cause of death worldwide, significantly impacting years of life adjusted for the degree of disability, particularly in developed nations. Given the statistics provided, it is clear that dyslipidaemia is a major cause of morbidity and mortality, making it a pressing public fitness. According to

India's nationwide fitness portal, dyslipidaemia affects roughly 25-30% of people living in cities and 15-20% of those in rural areas [5]. Despite being much more common among men, it affects individuals of all genders. In Ayurveda, the correlated condition to overweight is *Medoroga*, which is mentioned in (*Madhavanidan*) [6] and *Sharangdhara Samhitas* [7,8]. Ayurveda states that excessive consumption of *Kapha Aahar* leads to *Mandagni*, which in turn produces abnormal development of *Medo Dhatu*, which obstructs the *Strotas* and blocks *Vata Dosha*. Once *Vata* aggravates and returns to the *Pakvashaya*, the *Agni* becomes excited and requires frequent meals. *Medoroga* is the result of this continuous vicious cycle [9].

In *Ayurveda*, *Lekhan Basti* is the first option for treating dyslipidaemia and is regarded as a regular practice. The severity of the *Roga* and the virulence of the *Dosha* determine the treatment approach in *Ayurveda*. For *Bahu Dosha* (very vitiated *Dosha*), *Samshodhana* (bio-cleaning) *Chikitsa* is recommended; for *Alpa* and *Madhyama Bala Dosha* (mild to moderately vitiated *Dosha* and ailments), *Samshamana* (palliative) *Chikitsa* is used. Since *Medo Roga* is a condition where *Bahu Dosha* is dominating, *Samshodhana Chikitsa* is the most appropriate therapy method. The most effective treatment among these is *Basti Karma*, which balances *Vata Dosha*, the primary culprit in the pathophysiology of *Medoroga*. Several *Samshodhana* formulations suggested in

Medoroga are mentioned by *Acharya Sushruta*. Among them is *Triphala Gana*; nevertheless, researchers have not examined its effectiveness in treating dyslipidaemia [10]. "*Lekhana Vasti*" with "*Ushakadi Gana Dravyas*" utilises substances that counteract *Meda Dhatu* and exhibit potent *Teekshana* properties. Being *Tejo Guna Pradhana*, these drugs enhance digestive fire (*Jataragni*), promoting the metabolism of *Snigdhamsha* (unctuous) *Meda* while facilitating *Rukshana* (drying) of *Meda*. Through *Lekhan* (scraping) and *Chedana* (dissipating/clearing) actions, the circulation of *Meda* is effectively reduced [11].

Triphala has *Katu* and *Tikta rasa pradhana*, so it is *Dipana*, *Pachana*, *Tridoshashamana*, as well as *Lekhan* by virtue. It has a mild purgative action which causes *Vata anulomana*, therefore, it as one of the best natural colon cleansers. This characteristic play a key role in *Vatapradhana samprapti vighatana* in *Kostha*. *Triphala* stimulates *Jatharagni* and regulates the metabolism in the body by *Ama pachana*, encouraging the digestive system to work efficiently. This ensures that the fat taken in can be consumed appropriately and no unnecessary fat storage is in the body. Moreover, *Triphala* acts as *Rasayana* also, which leads to the formation of essential *Dhatu* and protects the body from injury due to vitiated *Dosha*, which improves blood circulation and increases immunity. Thus, the drug is seen as beneficial in breaking the *Dosha Dushyasam murchana* [12].

REVIEW OF LITERATURE

While modern medicine relies on statins for the management of dyslipidaemia, their long-term use poses risks like myopathy and liver dysfunction. Ayurvedic management emphasises *Samshodhana Chikitsa*, with *Lekhan Basti* being particularly effective due to its *Vata*-balancing and *Medohara* (lipid-reducing) properties. A study by Pooja BA et al., demonstrated significant reductions in lipid parameters using *Lekhan Basti* formulated with *Triphala*, *Madhu*, *Gomutra*, *Yavakshar*, and *Ushakadi Gana*. The results were attributed to improved liver function, reduced cholesterol absorption, and enhanced metabolic regulation. These findings support the integration of *Ayurvedic* interventions like *Lekhan Basti* in managing dyslipidaemia safely and holistically [13].

The contemporary approach to managing dyslipidaemia (*Medoroga*), particularly in high cardiovascular risk patients, heavily dependent on statins like atorvastatin. Despite its proven effectiveness in reducing LDL-C levels, research by Laufs U et al., indicates that only 10.5% of atorvastatin users reached the recommended LDL-C target of <70 mg/dL. Their cross-sectional study involving 2,625 high-risk ambulatory patients in Germany highlighted the underuse of high-dose atorvastatin; only 4.8% of patients received the maximum 80 mg dose, with an average daily dose being 28 mg. Despite guidelines advocating for LDL-C levels below 70 mg/dL, only a small fraction of patients met this goal, with the lowest success rate observed in diabetic individuals (7.5%). Notably, physician satisfaction with lipid management stood at over 62%, despite suboptimal LDL-C control. These insights reflect a broader trend of low-dose statin preference in clinical practice, emphasising the gap between evidence-based recommendations and real-world implementation, and underscoring the need for stricter adherence to guidelines and more aggressive lipid-lowering strategies in high-risk groups [14].

A study by Sharma A et al., evaluated the clinical efficacy of *Triphala Kwath* with *Madhu* and *Trikatu* capsules in managing dyslipidaemia. The trial demonstrated a statistically significant reduction in total cholesterol (41.82%), triglycerides (51.6%), LDL (62.22%), and VLDL (49.71%) in patients treated with the combination therapy, while HDL levels improved as well. These effects are attributed to the *Medohara*, *Deepana*, *Pachana*, and *Srotoshodhana* properties of *Triphala* and *Trikatu*, along with the synergistic and *Rasayana* action of *Madhu*. The study supports the use of classical Ayurvedic formulations as safe and effective options for the holistic management of dyslipidaemia (*Medoroga*) [15].

Study Objective

The present study aims to evaluate the efficacy of *Lekhan Basti* with *Ushakadi Gana* versus *Lekhan Basti* with *Triphala Gana* as against a standard control in dyslipidaemia (*Medoroga*).

1. To evaluate the efficacy of *Lekhan Basti* with *Triphala Gana* on lipid profile, BMI, and weight.
2. To evaluate the efficacy of *Lekhan Basti* with *Ushakadi Gana* on lipid profile, BMI, and weight.
3. To evaluate the efficacy of atorvastatin on lipid profile, BMI, and weight.
4. To compare the efficacy of *Lekhan Basti* with *Triphala Gana* as *Prakshep* against *Lekhan Basti* with *Ushakadi Gana* as *Prakshep* and standard control in the management of Dyslipidaemia (*Medoroga*) about lipid profile, BMI, and weight.

Null Hypothesis (H₀): There will be no significant difference between the efficacy of *Lekhan Basti* with *Triphala Gana* and *Ushakadi Gana* as *Prakshep*, or tablet atorvastatin, in the management of dyslipidaemia.

Alternative Hypothesis (H₁): *Lekhan Basti* with *Triphala Gana* is more efficacious than *Ushakadi Gana* or atorvastatin in managing dyslipidaemia (*Medoroga*).

MATERIALS AND METHODS

A randomised single (Assessor) blind three-arm superiority comparative controlled trial will be conducted at Mahatma Gandhi Ayurvedic College Hospital and Research Centre, Salod, Wardha, Maharashtra, India, from January 2025 to March 2026. The ethical approval from the Institutional Ethics Committee of the Mahatma Gandhi Ayurved College Hospital and Research Centre, Salod (H) Wardha, with registration number MGACHRC/IEC/June-2024/846, has been obtained before the commencement of the study. The trial is registered on the CTRI website under the number CTRI/2024/7/078111. The committee will oversee the trial's progress and determine its conclusion.

Inclusion criteria:

1. Patients willing to provide written informed consent.
2. Patients aged between 20 and 60 years.
3. Newly diagnosed dyslipidaemia patient with the following criteria [16]:
 - Serum cholesterol: 200 mg/dL - 239 mg/dL
 - Serum triglycerides: 150 mg/dL - 199 mg/dL
 - Serum HDL: >60 mg/dL
 - Serum LDL: >159 mg/dL
 - Serum VLDL: >30 mg/dL
4. Patient fit for *Basti* treatment.
5. Patients with a BMI between >24.9 kg/m² to 30 kg/m².
6. Patient with controlled hypertension.
7. Patients with controlled Type II DM (fasting: 100-130 mg/dL, postprandial 140-180 mg/dL).

Exclusion criteria:

1. Patients with known cases of cancer, tuberculosis, cardiac disorders, thyroid disorders, uncontrolled hypertension, haemorrhoids, fissures, or any other rectal disease.
2. Patients deemed ineligible for *Niruha Basti*.
3. Patients with uncontrolled Type II diabetes.
4. Pregnant and lactating women.
5. Patients with addictions to drugs, alcohol, or smoking.

Criteria for ending or changing allocated interventions:

1. Patients will be withdrawn if serum cholesterol exceeds 239 mg/dL.

2. Patients will be withdrawn if the BMI exceeds 30 kg/m².
3. Patients who choose to quit during the study will be allowed to do so and will be replaced.
4. Patients will be withdrawn if they develop any acute illness during the trial that may interfere with the study.
5. In case of untoward incidents, drug sensitivity, or any other health issue during the trial, the patient will be offered free treatment until the issue is resolved and such patients will also be withdrawn and replaced.

Calculation of the sample size: 129 (43 in each group).

$$n = \frac{(r+1) * p * (1-p) * \{Z(1-\alpha/2) + Z_{(1-\beta)}\}^2}{r * (p_2 - p_1)^2}$$

Where:

- $p = (p_1 + r * p_2) / (1 + r)$
- $Z_{(1-\alpha/2)}$: Z-score corresponding to the level of significance (α)
 $Z_{(1-\alpha/2)} = 1.96$ (for $\alpha=0.05$)
- $Z_{(1-\beta)}$: Z-score corresponding to the power of the test $Z_{(1-\beta)} = 0.84$ (for $\beta=0.2$)
- p_1 and p_2 : Proportions in Groups-1 and 2, respectively
- r : Ratio of Group-2 size to Group 1 size
- Proportion in Group-1 and of improvement in serum cholesterol *Lekhan basti* with *Ushakadi Gana* (p_1): 0.3753 [13]

Considering a 30% superiority

- Proportion in Group-2 (p_2): 0.6753
- Ratio (r): 1 (equal group sizes)

Total sample size = $3 * 43 = 129$.

Patients will be divided into three groups, each with 43 patients [Table/Fig-1]. [Table/Fig-2] shows CONSORT flowchart. The author or the researcher will enroll the participants, administer the intervention, and determine the allocation sequence. The drugs from *Ushakadi Gana* (*Yavakshar*, *Shuddh Shilajit*, *Tuttha*, *Hingu*, *Ushak*) and *Triphala Gana* (*Haritaki* (*Terminalia chebula*), *Bibhitaki* (*Terminalia bellirica*), *Amalaki* (*Phyllanthus emblica*)) [Table/Fig-3] will be procured from a certified retail source in Nagpur and standardised by the Department of Dravya Guna at Mahatma Gandhi Ayurvedic College, Hospital and Research Centre, Wardha [17]. Market preparations of Tab. Atorvastatin will be sourced from a reliable supplier.

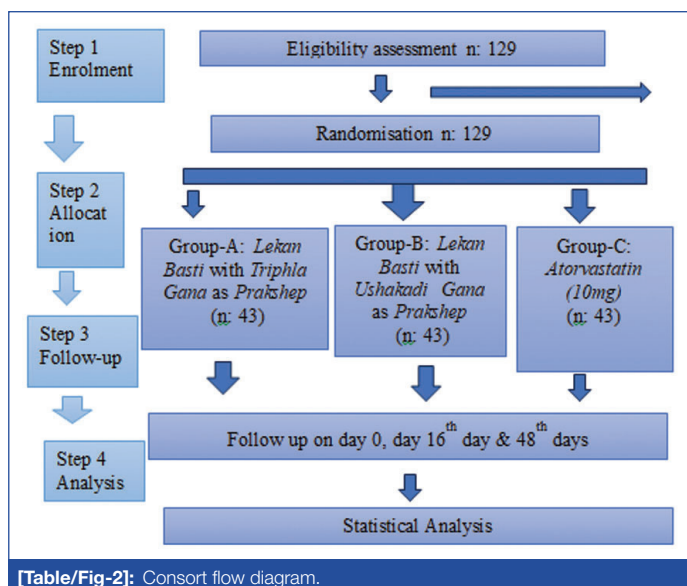
Group	Sample size	Intervention	Dose and frequency	Procedure time	Duration	Follow-up
A	43	<i>Lekhan Basti</i> with <i>Triphala Gana</i> as <i>Prakshep</i>	Empty stomach once in a day	30-60 min	16 days	0 day (base line), 16 th day, 48 th day
B	43	<i>Lekhan Basti</i> with <i>Ushakadi Gana</i> as <i>Prakshep</i>	Empty stomach once in a day	30-60 min	16 days	0 day (base line), 16 th day, 48 th day
C	43	Tab. Atorvastatin	1 10 mg OD after food	-----	48 days	0 day (base line), 16 th day, 48 th day

[Table/Fig-1]: Showing grouping and posology along with treatment duration and follow-up.

The formulation consists of three parts of *Haritaki* (*Terminalia chebula*), two parts of *Vibhitaki* (*Terminalia bellirica*), and one part of *Amalaki* (*Phyllanthus emblica*), with the fruit of each plant being used [18].

Preprocedure (*Poorvakarma*)

Instruments (*Sambhar Sangraha*): The equipment required for administering the decoction enema includes essential items such as cooking utensils, a stove, a grinder, and the necessary herbal ingredients (roots from thorny plants). Additional materials include honey, sesame oil, a measuring flask, a strainer, an enema pot, a



[Table/Fig-2]: Consort flow diagram.

catheter, a covering cloth, and an enema table. Supplementary items include potent herbal decoction mixtures, milder herbal decoction blends, and other remedies to manage any potential complications during the procedure.

Examination of the patient (*Atur Pariksha*): Assess the patient for fitness or unfitness for treatment. Evaluate the patient's condition, strength, as well as the severity of the disease using a comprehensive ten-factor diagnostic approach.

Formation of decoction enema: To prepare a decoction enema using *Triphala Churna*, start by combining 150 grams of the powder with 960 mL of water. Boil the mixture until the volume reduces to 240 mL, forming the decoction. In a separate clean vessel, measure the required amount of honey and blend it thoroughly with *Saindhav Lavana* until a uniform consistency is achieved. Gradually incorporate *Til Tail* (sesame oil) into the mixture, ensuring thorough blending. Next, add the prepared lukewarm decoction while stirring continuously. Strain the final solution using double layers of clean cotton cloth to remove any remaining solid particles. After straining, mix in the *Prakshep Dravya* and administer the enema at a lukewarm temperature.

This formulation consists of 200 mL of honey, 12 grams of *Saindhav Lavana*, and 300 mL of *Til Tail* (sesame oil). Additionally, 100 grams of *Kalka Dravya* (*Triphala Gana*) serve as the *Prakshep Dravya*, while 240 mL of the decoction is incorporated into the final mixture. Finally, *Gomutra* is added to complete the preparation [19].

Preparation of patients (*Atur Siddhata*): After eating a small meal that is neither too dry nor too oily, and which is no more than one-fourth of their typical portion size, the patient is encouraged to drink enough water. After the meal, they should take short walks to promote digestion and facilitate the elimination of waste. Following this, a session of oil application and warm therapy is recommended, including a thorough body massage using oil. After the massage, gentle heat therapy should be applied to the body. Mild warmth can help expel toxins and support the liquefaction of bodily fluids. Once the heat therapy is completed, a gentle full-body massage should be performed.

Main procedure (*Pradhanakarma*): The patient will be positioned on the massage table (*Droni*) in the left lateral position (*Vama Parshwa*), with the right leg flexed. Following lubricating the anal ridge and tip, one-fourth of the rubber catheter will be gently inserted into the anal canal, and lukewarm medicated oil will be gradually administered using an enema pot, ensuring it is held high to prevent obstruction. After the procedure, the catheter will be carefully removed to avoid complications.

Time for return decoction enema: The decoction enema should be returned within 48 minutes (1 Muhurta).

Name	Taste (Rasa)	Properties (Guna)	Potency (Veerya)	Post digestion effect (Vipaka)	Action (Karma)	Action on doshas (Doshghnata)
Haritaki (Terminalia chebula)	Pancharasa (except - lavan)	Laghu, ruksha	Ushna	Madhur	Rasayana, Swashara, Vayasthapani	Tridosahara mainly Vata shamaka
Vibhitaki (Terminalia bellirica)	Kasaya	Ruksha, Guru	Ushna	Madhur	Kasahara, jawarhara, virechanopaga	Tridosahara mainly Kaphahara
Amalaki (Phyllanthus emblica)	Panachrasa (except - lavan)	Laghu, Ruksha	Sheeta	Madhur	Vayahsthapana, rasayana, caksusya	Tridosahara mainly Pittahara

[Table/Fig-3]: Showing ayurvedic properties of the contents of Triphala gana [17].

Postprocedure (Paschat karma): Patients will be instructed to lie supine and relax. While in this state of relaxation, they should count up to 100 (100 Vak) to allow the decoction enema to disperse throughout the body. The practitioner will rub both palms and gently rub the patient's buttocks and back. Advise the patient to bathe with lukewarm water and to avoid excessive outdoors, daytime sleeping, extended travel, loud speaking, or expressing anger [19].

After retaining the herbal enema, a suitable diet such as light soups, meat broths, and similar nourishing foods should be provided. Additionally, lukewarm water should be used for drinking.

Lekhan Basti (Enema) will be administered in a specific order of *Anuvasan Basti* and *Niruha Basti*, as per the classical *Kaal Basti* pattern [20].

- On day 1, 2, 4, 6, 8, 10, 12, 14, 15, and 16, *Anuvasan Basti* (oil enema) will be administered.
- On day 3, 5, 7, 9, 11, and 13, *Niruha Basti* (decoction enema) will be administered [Table/Fig-3].

Outcomes

Objective parameters: Lipid profile:

Serum cholesterol: 200 mg/dL - 239 mg/dL
Serum triglycerides: 150 mg/dL - 199 mg/dL
Serum HDL: >60 mg/dL
Serum LDL: >159 mg/dL
Serum VLDL: >30 mg/dL [16]

- BMI: >24.9 kg/m² to 30 kg/m²
- Weight: Measured using the CROWN ELITE digital weighing scale (Mfg. Year: Oct. 2023)

These parameters will be assessed on day 0, the 16th day, and 48th day. The Gantt chart is shown in [Table/Fig-4].

Scholar/Investigator	Dr. Samiksha Satone							
Title	Comparative Efficacy of <i>Lekhan Basti</i> with <i>Ushkadi Gana</i> versus <i>Triphala Gana</i> as against standard control in Dyslipidaemia (<i>Medoroga</i>): A -RCT							
Steps	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8
Approval from IEC								
Review of the literature								
Drug preparation								
Enrollment of patient								
Data collection								
Statistical analysis								
Thesis writing								
Submission								

[Table/Fig-4]: Gantt chart.

STATISTICAL ANALYSIS

The data will be analysed using Statistical Package for the Social Sciences (SPSS) 17.0 software. Categorical variables within each group will be evaluated before and after treatment through an ANOVA test. Similarly, assessment parameters will be examined pre- and post-treatment using the ANOVA test. A p-value <0.05 will be considered indicative of statistical significance.

INTERVENTION MODIFICATION

Authors will notify the Ethical committee of any unfavorable side-effects. The patients will receive treatment for the negative effects experienced. If participants decide to stop the treatment, they must explain their reasons.

Dissemination: This procedure will also be made available as a thesis to promote the research. The study protocol includes a discussion of the methodology, data-gathering strategies, data-processing tactics, and ethical approval. We hope to expand the body of knowledge in this field and facilitate further research.

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- Plagiarism X-checker: Feb 01, 2025
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- iThenticate Software: May 31, 2025 (6%)

ETYMOLOGY: Author Origin**EMENDATIONS:** 6**AUTHOR DECLARATION:**

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- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

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