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EFFECT OF HOMEOPATHIC LECITHIN IN HYPERLIPIDAEMIA: AN OPEN-LABEL INTERVENTIONAL STUDY

ZANKHANA DESAI [1*] KETAN SHAH [2]

1. Corresponding Author: Community Medicine Department, Jawaharlal Nehru Homoeopathic Medical College, Faculty of Homeopathy, Parul University, Vadodara, Pin. 391760, India.
   Email- zankhana.desai@paruluniversity.ac.in. Contact number: 9825098025
2. Department of Homoeopathic Materia Medica, Ahmedabad Homoeopathic Medical College, Faculty of Homeopathy, Parul University, Ahmedabad, India.

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ABSTRACT

This open-label, single-arm clinical study investigated the effect of Lecithin homeopathic medicine on hyperlipidemia. Lecithin, a homeopathic medicine commonly used to address nutritional disorders, has also been suggested in the literature for the treatment of hyperlipidemia. Following screening, participants were recruited from outpatient department of homoeopathic medical college. They received Lecithin homoeopathic medicine in 6x potency, four pills taken orally per day for 6 weeks. Lipid profile was assessed pre and post intervention to evaluate primary outcome. A significant (p-values < 0.05) decrease in the mean value of high-density lipoprotein and an increase in low density lipoprotein and non-HDL were found in the preliminary analysis of 32 subjects. On the other hand, non-significant variations in mean value of triglyceride, VLDL, and total cholesterol were noted. Fisher's exact test, which measures the proportion change of participants in various lipid subcategories following intervention, showed no significant changes for HDL and Non-HDL. There were notable shifts in the percentage of participants in the TC and LDL subcategories of risk levels. Significantly, a shift in the percentage of participants to a lower risk category was noted for TG. Observed effects of Lecithin (6x) on lipid profiles were heterogeneous and inconclusive. However, the observed results suggest a possible role for Lecithin homeopathic medicine in modulating cholesterol metabolism through ACAT regulation, warranting further investigation.

INTRODUCTION

Hyperlipidaemia (ICD - 11, 5C80.2), a health disorder characterized by elevated levels of plasma lipids - including phospholipids, cholesterol, cholesterol esters, and triglycerides or lipoproteins such as low-density and very low-density lipoproteins, often accompanied by reduced high-density lipoprotein levels. This lipid imbalance is regarded as significant contributor to cardiovascular ailments. Currently, statins and fibrates serve as the most commonly prescribed medications for mitigating high triglyceride and cholesterol levels in plasma (Sheeba et al. 2021).

Hyperlipidaemia refers to a class of genetic and acquired diseases characterised by abnormally increased lipid concentrations in the body. Hyperlipidemia is highly prevalent, particularly in the Western Hemisphere, though it is also widespread in other regions. By a more formalized definition, it is a condition with lipoprotein, triglyceride, total cholesterol, or low-density lipoprotein (LDL) exceeding the 90th percentile compared to the overall population, or a high-density lipoprotein (HDL) level below the 10th percentile in relation to the broader population. Several studies and trials have consistently demonstrated that elevated levels of LDL cholesterol raise an individual's chance of acquiring atherosclerotic plaques and the vascular disease. On the other hand, HDL cholesterol helps control cholesterol levels, lowering the likelihood of atherosclerotic vascular disorders (Hill et al., 2023). Hansen et al. (2024) in their study mentioned that, "Although there is evidence of causality between LDL-C concentration and risk of ASCVD, LDL-C does not include the total atherogenic cholesterol burden and the predictive ability of LDL-C in statin-treated patients is limited. On the contrary, guidelines acknowledge that non-HDL-C is a measure of all atherogenic cholesterol and residual cholesterol-related risk is more accurately measured by non-HDL-C."

Lecithin

Lecithin is a fatty material containing phospholipids, specifically phosphatidylcholine, phosphatidylethanolamine, phosphatidylinositol, and other related compounds. It is often derived from sources such as soybeans, eggs, and sunflower seeds. Lecithin plays several important roles in the body. Lecithin being a crucial part of the membranes of cells, provides structural support and maintaining their integrity. Lecithin facilitates the absorption of fat-soluble vitamins such as A, D, E, and K. It enables emulsify dietary fats, facilitating their breakdown and absorption. Lecithin contains choline, a precursor to acetylcholine, which is a neurotransmitter involved in memory and muscle control. Choline, derived from Lecithin, is essential for liver health. It is involved in the metabolism of fats and lowering the likelihood of non-alcoholic fatty liver disorders by preventing accumulation of liver fat, Lecithin may have a positive impact on cardiovascular well-being by helping

in regulation of cholesterol. It is believed to enhance the solubility of cholesterol in the blood, potentially reducing the risk of atherosclerosis. A Lecithin-rich diet alters cholesterol regulation in the liver by augmenting the activity of 3-hydroxy-3-methylglutaryl coenzyme A reductase and cholesterol 7 alpha-hydroxylase, while lowering the activity of microsomal acyl-CoA: cholesterol acyltransferase (ACAT). One of Lecithin's most notable effects is its capacity to lower elevated LDL cholesterol levels. Additionally, it stimulates the liver to produce substantial amounts of HDL cholesterol (Mourad, et al. 2010).

Lecithin Homeopathic Medicine

Homeopathy, a form of alternative treatment that draws inspiration from "like cures like," where substances that would cause symptoms in a healthy individual, when diluted, are used to treat analogous symptoms in a diseased individual.

Commonly prescribed Homoeopathic medications encompass a broad spectrum, serving both acute and chronic conditions, and even constituting constitutional remedies. Conversely, medications with less established pathogenetic activities are categorized as uncommon or less familiar treatments. These remedies are typically prescribed based on symptomatic indications for particular diseases or organ afflictions. They hold significant importance in managing patients with unilateral diseases, particular pathological conditions, advanced stages of illness, or those requiring palliative care. Lecithin, a homeopathic medicine, falls under the category of partially proven medicines, with much of its therapeutic applications discerned through clinical observation.

As mentioned in Pocket manual of Homoeopathic Materia Medica Boericke, Lecithin is important in the vital processes of plant and animal organisms (Boericke, 2023).

This drug specifically addresses nutritional issues, especially those involving blood. It helps in nutritional improvements in cases of tuberculosis, maintaining haemoglobin levels and during lactation aids in improving nourishment quality and secretion of milk.

This medicine aids in health improvement for conditions characterized by symptoms of general deterioration, such as fatigue, weakness, shortness of breath, and weight loss.

For gastrointestinal issues, it addresses appetite loss, digestive disturbance, abdominal bloating, and stomachache that may radiate to the throat. It is also support to manage urinary concerns, including phosphaturia (excess phosphate in the urine), albuminuria (presence of albumin in the urine), and glycosuria (presence of sugar in the urine). Additionally, it is prescribed for mental health issues such as mental exhaustion, forgetfulness, anxiety, insomnia, restlessness, and aversion to mental work.

The effectiveness of this medication has been the subject of less research; most of it has concentrated on its advantages for anaemia and not shown any significant adverse effects (Sharma et ai., 2018, Tripathy et al., 2021, CCRH, 2005).

Due to the unique properties of the medicine in treating nutritional disorders, certain clinical recommendations are for the use of this medicine for managing lipid disorders (Balakrishan, 2004, Gopi, 2022, Tarkas, 2002, Gupta et al., 2021).

It is believed to have benefits for lipid metabolism, but its use in treating hyperlipidemia is not well-established through scientific research.

On the hypothetical base involving the concept that Lecithin's natural benefits for lipid disorder could be mirrored in a diluted homeopathic form, this study was conducted to understand effect of homoeopathic medicine Lecithin in hyperlipidaemia from a clinical standpoint and to recognize any beneficial effect of the medicine in lipid disorders. It serves as preliminary assessment of the medicine's effect on hyperlipidaemia.

MATERIALS AND METHODS

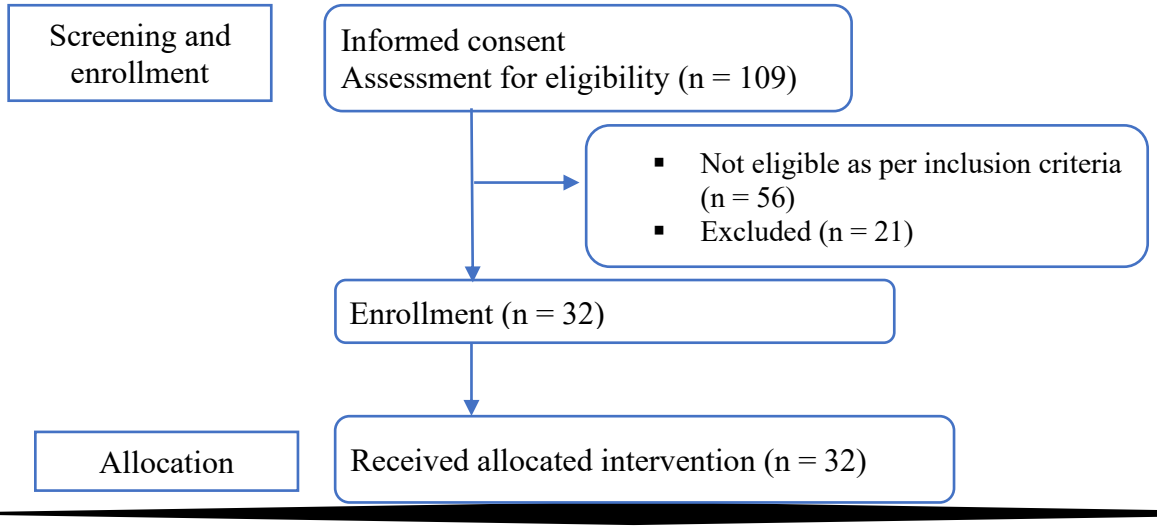
This open-label, prospective, pre-post comparison, single-arm clinical study was conducted to know effect of the Lecithin homeopathic medicine. To recruit participants, the conventional sampling technique was used. After obtaining informed consent, interested participants were screened and enrolled based on eligibility criteria from outpatient department (Practice of Medicine) of a Jawaharlal Nehru homoeopathic medical college hospital. (From February to November 2023) The study included patients aged between 30 to 70 years diagnosed with hyperlipidaemia who were not on any medication for the condition. Exclusion criteria were those who are unwilling to take part in study, pregnant or breastfeeding women, subject reported history of HIV, Severe or uncontrolled systemic/metabolic illness, heavy Alcoholics, taking oral contraceptive pills, steroid therapy.

Homoeopathic medicine in 6x potency means the substance has been diluted to one part in 1,000,000 (1:1,000,000). Lower potencies are typically used in homeopathic systems that emphasize the organotropic effects of remedies. In this study, the 6x potency was selected to avoid any material effects of Lecithin that could occur with even lower potencies. A minimum dose of 4 pills per day orally for six weeks of this 6x potency was given to assess the medicine's effect on lipids.

The medicine was obtained from a reputable homeopathic pharmacy. Participants were advised to maintain their usual dietary habits during the treatment period. They were followed on a weekly basis or as needed throughout the course of intervention.

Lipid profile changes pre and post intervention were considered for primary endpoint assessment. Other clinical laboratory investigations were conducted for parameters including-complete blood count, serum glutamic-pyruvic transaminase (SGPT), serum glutamic-oxaloacetic transaminase (SGOT), Glycated haemoglobin (HbA1c), serum creatinine, and urine analysis at the beginning of study and after 6 weeks of intervention. Data were analysed by use of excel and SPSS version 25.

Ethical clearance (Ref. No. 006/JNHMC/IECHR/20) was obtained from the Institutional Ethics Committee for Human Research, and this study is registered in the Clinical Trial Registry India (CTRI/2022/04/041953).



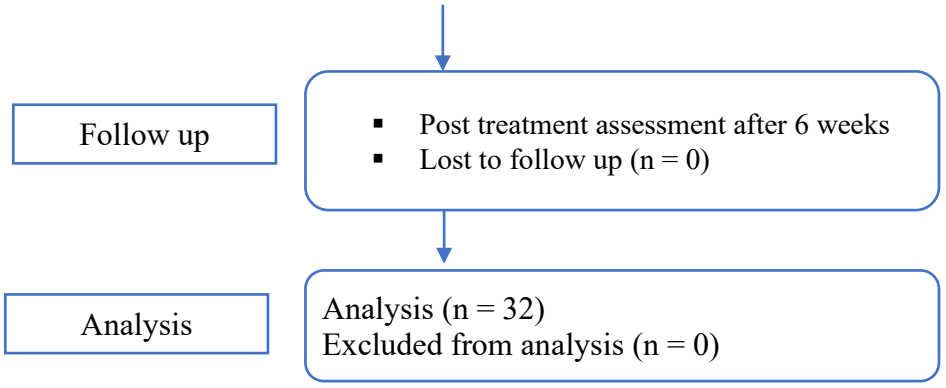


Fig. 1: Flow diagram of the clinical study

RESULTS AND DISCUSSION

Descriptive statistics

Out of the 32 participants, 34.38% were in the 41 to 50 age group, 31.25% were in the 51 to 60 age group, 21.88% were in the 61 to 70 age group, and 12.5% were in the 30 to 40 age group. The mean age was 53.06 years, with a range from 39 to 70 years. Among the participants, 37.5% were male (Total = 12) and 62.5% were female (Total = 20), indicating a higher proportion of females. The mean body mass index (BMI) was 26.1 in male participants and 28.1 in female participants. There was minimum non-significant change in the values of HbA1c and Haemoglobin in male and female group.

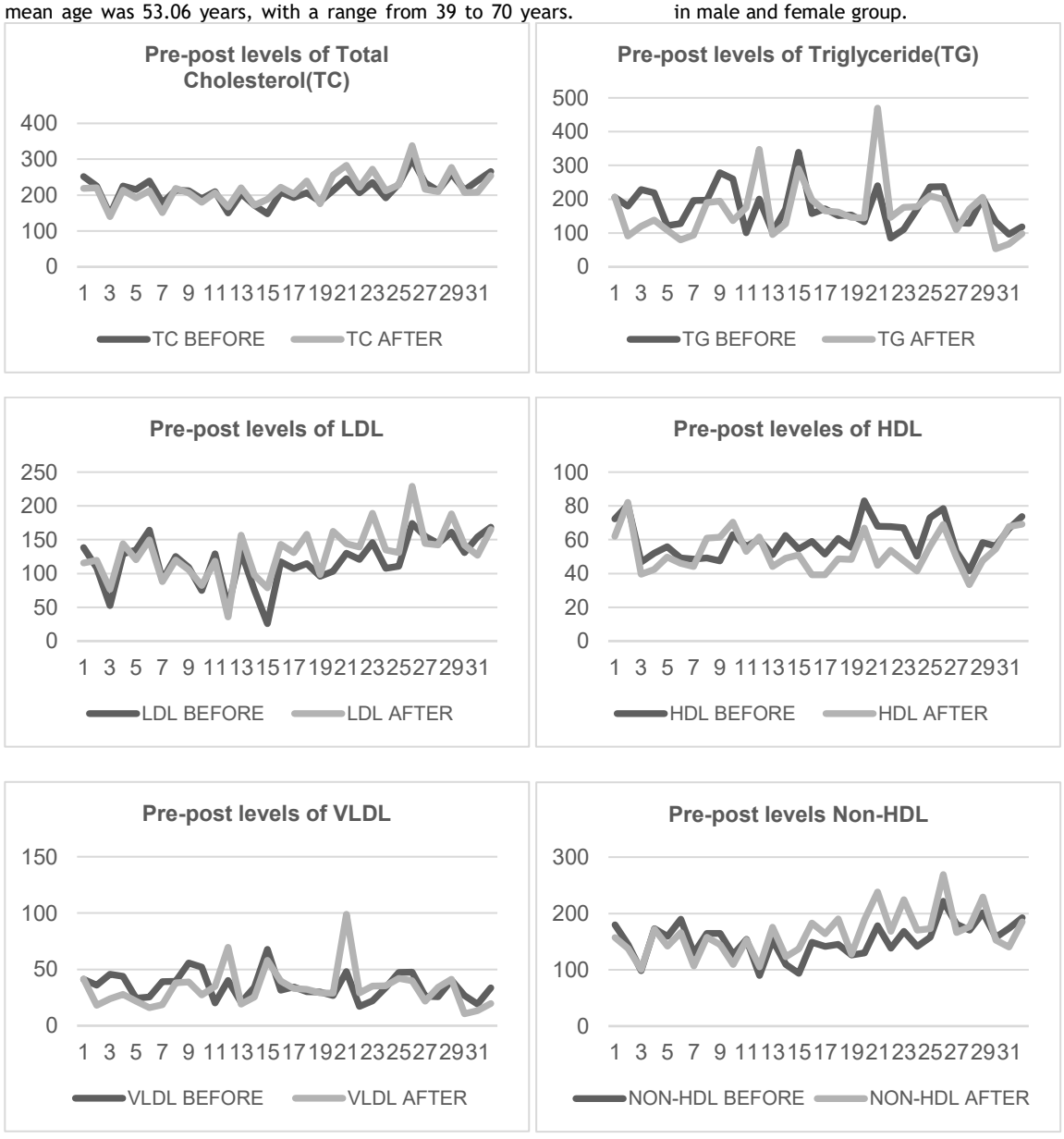


Fig. 2: Lipid levels pre and post intervention.

The findings of this study present a diverse range of responses among patients following the intervention, particularly in the context of lipid level changes. (Fig. 2) The majority of patients exhibited stability within the same level of lipid categories as observed at baseline assessment. However, a notable subset experienced reductions to lower risk levels, while others showed an increase in levels.

Analysis for significance

Table 1: Comparing lipid values pre-post intervention

Category		Minimum	Maximum	Mean ($\bar{x}$)	Standard Deviation (S)	Median	Paired t test p – value (α = 0.05) (2-tailed) df = 31 95% Confidence Interval
TC	Pre	145	300	213.03	34.27	212.5	t = 0.9 p = 0.373
	Post	140	338	216.56	39.86	213	
TG	Pre	85	339	174.59	59.89	170.2	t = 0.7, p = 0.483
	Post	53.3	469.6	165.43	82.9	153.95	
LDL	Pre	25.8	174.1	118.17	35.22	123.2	t = 3.07 p = 0.004
	Post	35.74	229.02	130.57	37.55	132.96	
HDL	Pre	41.6	83	59.78	10.67	57.35	t = 4.5 p = 0.000
	Post	33.4	82.1	52.96	11.34	49.75	
VLDL	Pre	17.16	67.8	35.21	11.81	34.04	t = 0.7 p = 0.472
	Post	10.6	98.92	33.24	17.19	30.79	
NON-HDL	Pre	89.9	221.6	153.25	30.74	155.85	t = 2.17 p = .037
	Post	100.5	269	163.6	38.9	164.85	

Note: Non-HDL calculated by subtracting HDL cholesterol from total cholesterol value.

Following the intervention, there was an observed increase in the variability of lipid levels, particularly for triglycerides, as indicated by the standard deviations. The mean values showed increase in total cholesterol (1.66%), LDL (10.49%) and NON-HDL (6.32%), while decreased mean value observed for triglyceride (5.25%), HDL (11.41%), and very low-density lipoprotein (5.60%) levels. The median values indicated improvements in triglyceride (TG) and VLDL levels, but a rise in LDL levels and a decrease in HDL levels were also noted (Table 1).

The paired t-test results showed a negligible, non-significant difference between the mean values of total cholesterol, triglycerides, and VLDL before and after treatment. Analysis using the paired t-test demonstrated a substantial difference in the mean values of HDL, LDL and NON-HDL after treatment. (*p* value > 0.05) The correlations for all lipid variables before and after treatment are statistically significant, with less than 0.05 *p*- value (Table 1).

Table 2: Analysis for proportion change of participants across Lipid categories Fisher's exact test

Lipid Categories	Sub categories	BEFORE		AFTER		p – value (α = 0.05) 95% Confidence Interval Two tailed	Result
		No. of Patients	%	No. of Patients	%		
HDL	Normal	27	84.4	22	68.8	0.293	Non-Significant
	Low Female: <50 mg/dL male: <40 mg/dL	5	15.6	10	31.3		
TG	Optimal <100 mg/dL	2	6.3	6	18.8	0.034	Significant
	Normal <150 mg/dL	10	31.3	10	31.3		

	Borderline High 150–199 mg/dL	9	28.1	10	31.3		
	High 200–499 mg/dL	11	34.4	5	15.6		
	Very High >499 mg/dL	0	0.0	1	3.1		
LDL	Optimal <100 mg/dL	7	21.9	7	21.9		
	Near Optimal 100–129 mg/dL	12	37.5	7	21.9		
	Borderline High 130–159 mg/dL	8	25.0	13	40.6	<0.001	High Significant
	High 160–189 mg/dL	5	15.6	4	12.5		
	Very High >189 mg/dL	0	0.0	1	3.1		
TC	Desirable <200 mg/dL	10	31.3	9	28.1		
	Borderline High 200–239 mg/dL	16	50.0	17	53.1	<0.001	High Significant
	High >239 mg/dL	6	18.8	6	18.8		
Non-HDL	Optimal <130 mg/dL	6	19	6	19		
	Near Optimal 130–159 mg/dL	12	38	9	28		
	Borderline High 160–189 mg/dL	10	31	12	38	0.53	Non-Significant
	High 190–219 mg/dL	3	9	1	3		
	Very High >220 mg/dL	1	3	4	13		

Proportional changes in lipid subcategories were evaluated using Fisher's exact test. The analysis revealed no statistically significant changes for high-density lipoprotein (HDL) and non-high-density lipoprotein (Non-HDL). In contrast, significant alterations were observed in the proportions of participants across categories for total cholesterol (TC), low-density lipoprotein (LDL), and triglycerides (TG). ($p > 0.05$) Specifically, for TC and LDL, there was a significant shift towards higher level lipid categories. In contrast, for TG, a favorable trend was observed, with a greater proportion of participants transitioning to lower level TG categories compared to those in higher categories. (Table 2)

DISCUSSION

Homoeopathic remedies are highly diluted, and the principles behind homeopathy differ significantly from conventional medicine. A process of serial dilution, along with vigorous shaking (succussion) creates solutions so diluted that they often contain only nanomolecules of the original substance, which is used in medicine preparation. This approach contrasts sharply with conventional medicine, which typically uses pharmacological doses to target specific biological mechanisms or pathogens. Homoeopathic medicine through dynamic action helps the body's self-healing mechanisms.

In homeopathy, medicines are used in various potencies, ranging from low to high. While there is no exact criterion to define high and low potency, for practical purposes, a cutoff of 12C potency is often considered. This is based on Avogadro's constant, beyond which the medicinal substance is no longer traceable and exists as nanoparticles in higher dilutions. This various potency exhibits different potential therapeutic effects. Low dilutions are significant in homeopathic prescribing, especially in methods that emphasize the organotropic effects of homeopathic remedies, which are integrated with conventional medical diagnoses and treatments (Jutte, 2005, Kokornaczyk et al., 2019). Organotherapy is a more "simplified" approach to homeopathy, where remedies have a lower degree of symptom similarity but are aimed at treating specific organs or systems.

A search indicated that very few studies have looked into the use of homoeopathic medicine for hyperlipidaemia; further research is necessary to identify any possible advantages of homeopathy in this condition. One case series study with Fucus vesiculosus shown significant reduction in triglyceride levels and improvement in lipid profiles (Ponnam et al., 2021). Gautteria gaumeri, a homoeopathic remedy, was found to be an effective treatment for hypercholesterolaemia in a prospective single arm clinical study carried out in northern India (Husain et al., 2017). Furthermore, a study conducted in vitro revealed that homoeopathic preparations of Colchicum autumnale may have cholesterol-lowering properties, suggesting that they could be useful in the treatment of hypercholesterolaemia (Nithya et al., 2022). Nonetheless, a double-blind, randomised, placebo-controlled study found that, when compared to a placebo, the homoeopathic Dioscorea villosa 6CH preparation had no discernible impact on dyslipidaemia (Naskar et al., 2020).

In conventional therapy, research studies have indicated that Lecithin supplements have been shown to help lower hypercholesterolemia and high triglyceride levels (Brrok et al., 1986, Simon et al., 1977, Spilburg et al., 2003, Onaolapo et al., 2024).

The research aimed to elucidate the possible effects of Lecithin in 6x potency on hyperlipidaemia. The result of paired t-test analysis showed a non-significant and very small difference in the mean values of total cholesterol (1.66% increase), triglycerides (5.25% decrease), and VLDL (5.60% decrease), However, significant difference were observed in the mean values of HDL, LDL and Non-HDL after intervention ($p > 0.05$). The median values show a reduction in TG and VLDL, but an increase in LDL and a decrease in HDL. The analysis of changes in lipid category proportions using Fisher's exact test revealed opposite trends for total cholesterol (TC) and low-density lipoprotein (LDL), while triglyceride (TG) levels showed improvement. Overall finding suggests that there were observed changes in mean values of lipids and also significant alterations in distribution of participants across lipid profile categories.

A study on rats has shown that Lecithin supplementation can mimic the effects of Acyl-coenzyme A: cholesterol

acyltransferase (ACAT) inhibitors by reducing ACAT activity and altering lipid metabolism. Diet intervention also drastically reduced ACAT activity and plasma VLDL, as well as their triglyceride and cholesteryl ester content. Thus, Lecithin feeding mimics the effect of drug-induced inhibition of ACAT activity (Leblanc et al., 2003). Lecithin supplementation had no appreciable impact on HDL or IDL levels. However, it increased LDL.

ACATs are membrane-bound enzymes responsible for converting free cholesterol into cholesteryl esters using long-chain fatty acyl-CoA. This reaction is essential for regulating intracellular cholesterol levels by enabling cholesterol storage.

In human trials, the ACAT inhibitor CI 1011 was found to lower VLDL cholesterol and triglycerides, although it did not significantly affect LDL cholesterol levels (Chang et al., 2009).

The findings of this study highlight the possible similar effect of Lecithin homeopathic medicine in modulating cholesterol metabolism through ACAT regulation.

These study results underscored the complexity of lipid level changes after intervention, showing that patients with this sample population responded differently to homoeopathic medicine Lecithin. The medicine had varying effects on triglycerides and cholesterol. The mechanisms underlying these different actions are beyond the scope of this study.

CONCLUSION

The findings provided valuable insights into the effect of Lecithin as a homeopathic medicine on lipids. However, the results were inconsistent, with significant variability in participants' responses. Given the conflicting evidence surrounding the effects of ACAT inhibition, future studies should explore the potential of Lecithin homeopathic medicine through robust biomarkers. Investigating this alternative approach may offer insights into novel, non-pharmacological strategies for managing lipid disorders.

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Declarations:

Ethical statement

Ethical clearance was obtained from the institutional Ethics committee for Human Research, Jawaharlal Nehru Homoeopathic Medical College. Ref. No. 006/JNHMC/IECHR/20. Clinical trial registry India, CTRI Number: CTRI/2022/04/041953. Written Informed consent was obtained from all participants before enrolling them.

Conflict of interest:

The authors declare that they have no conflicts of interest.

Data Availability

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Author's contribution:

Concepts: Desai Z., Shah K.

Literature search, experimental studies, data acquisition, and data analysis: Desai Z.

Manuscript preparation: Desai Z., Shah K.

Manuscript editing, manuscript review, final approval of the version to be published: Desai Z., Shah K.

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