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ORIGINAL ARTICLE

OPEN LABEL SINGLE CENTRIC CLINICAL EXPLORATORY OF EFFICACY STUDY ON DELIPO CAPSULE, AN AYURVEDIC PROPRIETARY FORMULATION

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ABSTRACT

Introduction: Obesity and hypercholesterolemia are significant global health concerns, contributing to metabolic disorders such as cardiovascular disease and type 2 diabetes. Conventional treatments often include pharmacological interventions and lifestyle modifications, which may have limitations in terms of adherence and side effects. Ayurvedic medicine offers a holistic approach to weight management and metabolic regulation. DELIPO CAPSULE, a proprietary Ayurvedic formulation, has been developed to address symptoms associated with obesity, including shortness of breath, fatigue, excessive sweating,, difficulty in sleeping and high LDL cholesterol levels. **Objective:** The primary objective of this study was to evaluate the clinical efficacy of DELIPO CAPSULE in managing symptoms of obesity and hypercholesterolemia. **Methods:** The study aimed to assess its impact on weight management, cholesterol levels, and associated symptoms over a 30-day treatment period. This Phase-II-A, single-center, open-label, therapeutic exploratory clinical trial was conducted on 20 patients diagnosed with obesity-related conditions. Participants were administered 1-2 DELIPO CAPSULES twice daily with lukewarm water for 30 days. Clinical and laboratory assessments were performed at baseline (day-1) and post-treatment (day-30). Ethical approval was obtained, and written informed consent was secured from all participants. **Results:** After 30 days of treatment: 75% (15 patients) experienced significant symptom improvement. 15% (3 patients) showed moderate improvement. 5% (1 patient) had mild improvement. 5% (1 patient) dropped out of the study. Laboratory investigations confirmed improvements in cholesterol levels and metabolic markers. **Conclusion:** DELIPO CAPSULE demonstrated significant efficacy in managing obesity-related symptoms and metabolic imbalances. The findings support its potential as a safe and effective Ayurvedic intervention for weight management and hypercholesterolemia.

Keywords: Obesity, Hypercholesterolemia, Metabolic disorders, Ayurvedic medicine

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INTRODUCTION

Obesity and hypercholesterolemia are among the most significant public health concerns worldwide, contributing to an increased risk of metabolic disorders such as type 2 diabetes mellitus, hypertension, and cardiovascular disease[1]. According to the World Health Organization (WHO), global obesity rates have nearly tripled since 1975, with more than 650 million adults classified as obese in 2016[2]. This alarming rise in obesity prevalence is attributed to various factors, including sedentary lifestyles, high-calorie diets, genetic predisposition, and metabolic dysfunction[3].

Pathophysiology of Obesity and Hypercholesterolemia

Obesity is a multifactorial disorder characterized by excessive fat accumulation due to an imbalance between caloric intake and energy expenditure[4]. The condition is closely linked to metabolic syndrome, insulin resistance, and chronic low-grade inflammation, which collectively increase the risk of cardiovascular diseases[5].

Adipose tissue acts as an endocrine organ, secreting pro-inflammatory cytokines such as tumor necrosis factor-alpha (TNF-α) and interleukin-6 (IL-6), which contribute to systemic inflammation and metabolic dysfunction[6].

Hypercholesterolemia, characterized by elevated levels of low-density lipoprotein cholesterol (LDL-C) and decreased levels of high-density lipoprotein cholesterol (HDL-C), is a major risk factor for atherosclerosis and coronary artery disease[7]. Excess LDL-C leads to the formation of arterial plaques, reducing vascular elasticity and increasing the likelihood of heart attacks and strokes[8]. Additionally, obesity-induced insulin resistance exacerbates dyslipidemia by impairing lipid metabolism and increasing triglyceride levels[9].

Challenges in Conventional Management

Conventional treatments for obesity and hypercholesterolemia primarily include lifestyle modifications, pharmacotherapy, and, in severe cases, bariatric surgery[10]. Dietary interventions focusing on calorie restriction and macronutrient balance are recommended as first-line management strategies. However, adherence to dietary changes remains a challenge due to behavioral and environmental factors[11]. Regular physical activity is essential in weight management, but many individuals find it difficult to maintain consistent exercise routines due to work constraints and lack of motivation[12].

Pharmacological treatments such as statins for hypercholesterolemia and appetite suppressants for obesity are widely used. Statins lower cholesterol levels by inhibiting HMG-CoA reductase, the enzyme responsible for cholesterol synthesis[13]. However, long-term statin use has been associated with adverse effects, including muscle pain, liver dysfunction, and increased risk of type 2 diabetes[14]. Similarly, weight-loss medications like orlistat and liraglutide have shown effectiveness but may cause gastrointestinal discomfort, nausea, and other side effects[15].

Bariatric surgery, including gastric bypass and sleeve gastrectomy, is an option for morbidly obese individuals who do not respond to lifestyle and pharmacological interventions. While effective, these procedures carry risks such as nutritional deficiencies, post-surgical complications, and long-term metabolic changes. Given these challenges, there is a growing interest in alternative and complementary therapies, including Ayurvedic medicine, for managing obesity and metabolic disorders.

Ayurveda and Its Role in Metabolic Disorders

Ayurveda, the traditional system of medicine practiced in India for over 5,000 years, offers a

holistic approach to weight management and metabolic health. Ayurvedic treatments emphasize restoring balance in bodily functions through herbal formulations, dietary modifications, and lifestyle changes. Various Ayurvedic herbs have been studied for their potential to regulate lipid metabolism, reduce inflammation, and promote weight loss without causing adverse effects.

DELIPO CAPSULE: An Ayurvedic Approach to Obesity Management

DELIPO CAPSULE, a proprietary Ayurvedic formulation, has been developed as a natural intervention for obesity and hypercholesterolemia. The formulation consists of carefully selected herbal ingredients known for their lipid-lowering, metabolism-boosting, and anti-inflammatory properties. Ayurvedic herbs such as Guggulu (Commiphora mukul), Triphala (a combination of Terminalia chebula, Terminalia bellirica, and Emblica officinalis), and Punarnava (Boerhaviadiffusa) have demonstrated efficacy in reducing cholesterol levels, promoting fat metabolism, and improving digestive health[21].

Guggulu is well known for its ability to regulate lipid metabolism and reduce LDL cholesterol while increasing HDL cholesterol levels[22]. Clinical studies have shown that Guggulu extracts can significantly lower total cholesterol and triglyceride levels, making it a promising natural alternative to statins.

Triphala, a combination of three potent antioxidant-rich fruits, has been traditionally used in Ayurveda for detoxification and weight management[24]. Studies suggest that Triphala helps regulate lipid profiles, improve insulin sensitivity, and enhance gut microbiota balance, contributing to weight loss.

Punarnava is a well-documented diuretic and anti-inflammatory herb that aids in reducing water retention, improving digestion, and supporting liver function[26]. It is particularly useful in obesity-related complications where excess fluid accumulation and poor metabolism are concerns. Other ingredients in DELIPO CAPSULE work synergistically to enhance metabolic rate, improve fat oxidation, and maintain overall metabolic balance.

Scientific Validation of Ayurvedic Interventions

Despite the historical use of Ayurvedic medicine, scientific validation through clinical trials is essential for its integration into modern healthcare. The lack of standardized formulations, variability in herbal composition, and limited large-scale studies has been challenges in Ayurveda's widespread acceptance[29]. However, emerging clinical research supports the efficacy of Ayurvedic interventions in metabolic disorders, highlighting their potential as safe and effective alternatives.

Objective of the Study

The primary objective of this study is to clinically validate the efficacy of DELIPO CAPSULE in reducing obesity-related symptoms, including shortness of breath, fatigue, excessive sweating, difficulty in sleeping, and high LDL cholesterol levels. The study aims to evaluate patient-reported outcomes and laboratory investigations before and after a 30-day treatment period.

By bridging the gap between traditional knowledge and modern scientific validation, this study seeks to provide evidence-based support for DELIPO CAPSULE as a viable therapeutic option for weight management and metabolic health. The findings of this research could contribute to the broader acceptance of Ayurvedic formulations in obesity management while offering a natural, side-effect-free alternative to conventional pharmacotherapy[31].

METHOD AND MATERIALS:

Description of the population to be studied

The population of Salem city is more than 10,00,000, and the estimated prevalence rates of patients with "Shortness of breath, Fatigue, Excessive sweating, Difficulty in sleeping, High LDL cholesterol level in blood, found in Athisthoolaroga (excess weight), Sthoulyaroha (Obesity) and Medhoroha (Hypercholesteremia)" etc. shall be more than 10 % in the area. To recruit the participants, we had advertised in the Social media (friend's groups, Local groups, Private Siddha/Ayurveda doctor groups, and on the Facebook pages of Siddha/Ayurveda hospitals and creating awareness in public exhibitions.

Responsibility of potential risks and benefits, if any, to human subjects

As per Siddha/Ayurveda textual references found in First schedule (section 3a) of Drugs and cosmetic act 1940, and scientific research studies done anywhere regarding the herbal ingredients found in the formula supplied by the manufacturing unit, an Undertaking has been obtained from the Manufacturer of the product that the Sample supplied for clinical trials contains only the herbal ingredients mentioned in the references found in first schedule Siddha/Ayurveda classical texts.

The Clinical research center has recruited the patients willing for the study after obtaining their written consent and provided the medicine in the prescribed dosage indicated in the package under the supervision of qualified Siddha/Ayurveda physician.

It has been clarified to the manufacturer that any Metals if included in the formula should conduct Toxicity studies and Pre-clinical animal studies before conducting clinical trials, and it was also clarified that the Manufacturer of the product is solely responsible for potential risk - if any, to human subjects undergoing this clinical study.

Quality control and quality assurance

The Manufacturing Unit of the drug is responsible for the hygienic packaging of the dose of the herbal product to be dispensed to the participant. The label should necessarily contain the word "For Clinical studies only".

Description of and justification for, the route of administration, dosage, dosage regimen, and treatment period.

Route of Administration Dosage - Oral usage
Dosage - 1-2 capsules bds with 100 ml lukewarm water.
Dosage regimen - Morning and night, after food.
Treatment period - 30 days.

Trial study center

The centre of study is, Outpatient department. CRO - Ashram Siddha research institute, Swarnapuri, Salem city, Salem district.

IEC clearance

The prospective Phase-II-A, Single center, Open label, Therapeutic exploratory clinical trials is duly approved by the INSTITUTIONAL ETHICAL COMMITTEE FOR CLINICAL RESEARCH OF THECRO, Ashram Siddha Research Institute, constituted under Rule-7 and registered under Rule-8 of The Central Drugs Standard Control Organization (CDSCO) under Directorate General of Health Services, Ministry of Health and Family welfare, Govt. of India as per Ethical guidelines for Biomedical Research on Human subjects 2006 issued by AYUSH-ICMR guidelines. All patients were obtained with written informed consent.

Sample size and Period of study

Enrollment: 20 patients

Study Start Date: 29.11.2024
Study Completion Date: 31.12.2024

Screening of Patients for study

In the present study, patients suffering from symptoms like "Shortness of breath, Fatigue, Excessive sweating, Difficulty in sleeping, High LDL cholesterol level in blood, found in Athisthoolaroga (excess weight), Sthoulyaroha (Obesity) and Medhoroha (Hypercholestraemia)" etc. was taken for study. The Inclusion and exclusion were made by recording their past history and through clinical examination. After recruitment, all follow-up visits were performed at the same hospital by qualified Siddha/Ayurveda graduate investigators in keeping with the protocol.

Obtaining patient consent

Whenever a patient is included in the study a consent form in his mother tongue (enclosed) detailing the procedures with side effects if any, benefits from the treatment, was explained and details of the follow up visit was also explained. The procedure for referral clause, withdrawal, and adverse effects was explained thoroughly.

Criteria for Inclusion

Patients above 20 years and below 60 years, suffering from clinical symptoms like "Shortness of breath, Fatigue, Excessive sweating, Difficulty in sleeping, High LDL cholesterol 1-level in blood, found in Athisthoolaroga (excess weight), Sthoulyaroha (Obesity) and Medhoroha (Hypercholes-traemia)" etc. was taken for study.

Criteria for Exclusion: Participants will be excluded if they are above 60 years, experiencing or have a history of the following: Osteo arthritis, history of drug/alcohol abuse, night/shift-work employment, Diabetic complications, Psoriatic arthritis and any endocrine disorders.

Criteria for withdrawal

During the course of the trial, if any serious conditions develop (or) the symptoms aggravate which requires urgent treatment, such subjects may be withdrawn from the trial..

Outcome measure:

Routine Examination and assessment as per Indian Medicine Physiology

The complete History and physical examination of the patients along with Envagaithaervu, tridoshanaadi, saptha dhatu thaervu etc. were recorded in a case sheet on first day. The second Clinical assessment was done on 30th day of treatment.

Blood test: Blood samples were obtained the same day when each session was initiated. Participants reported to the hospital between 09:00 am and 10:00 am, after overnight fasting, for blood withdrawal from the antecubital vein. Samples were analyzed using routine automatic techniques in the prescribed laboratory. All follow-up visits scheduled for this trial were performed at the referral hospital by the registered investigators.

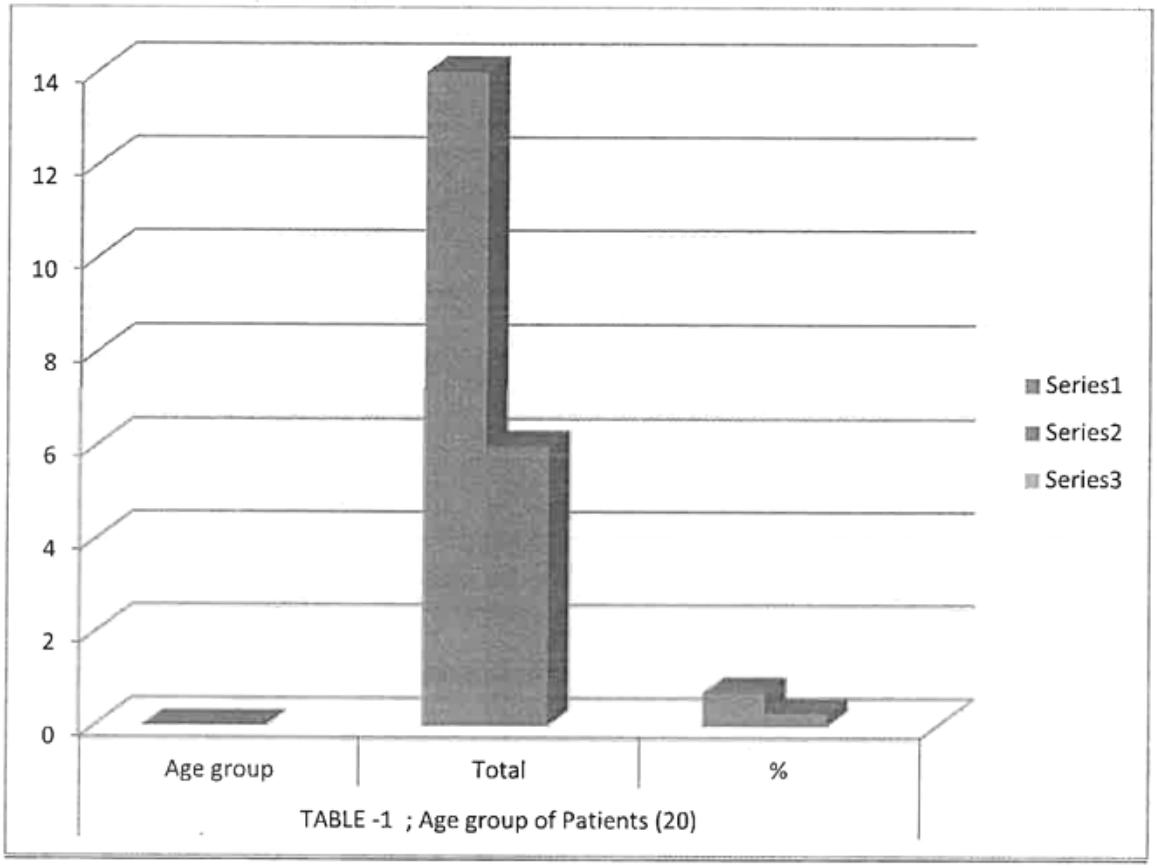
Intervention: The patients were provided with Ayurvedic proprietary medicine — DELIPO CAPSULE, and advised to take 1-2 capsules, Morning and evening. As Lifestyle management with diet and exercise can improve the condition and patient self-management life style changes were advised.

Success indicators: Reduction of minimum 10 percent in symptoms at baseline and at the completion of treatment in the words of the patient, and measured as per the physician's conscience, can be taken as Success indicator.

Discussion and Statistical analysis of the Results Obtained;

TABLE -1 ; Age group of Patients (20)

Age group	Total	%
21-45	14	72%
45-60	6	28%

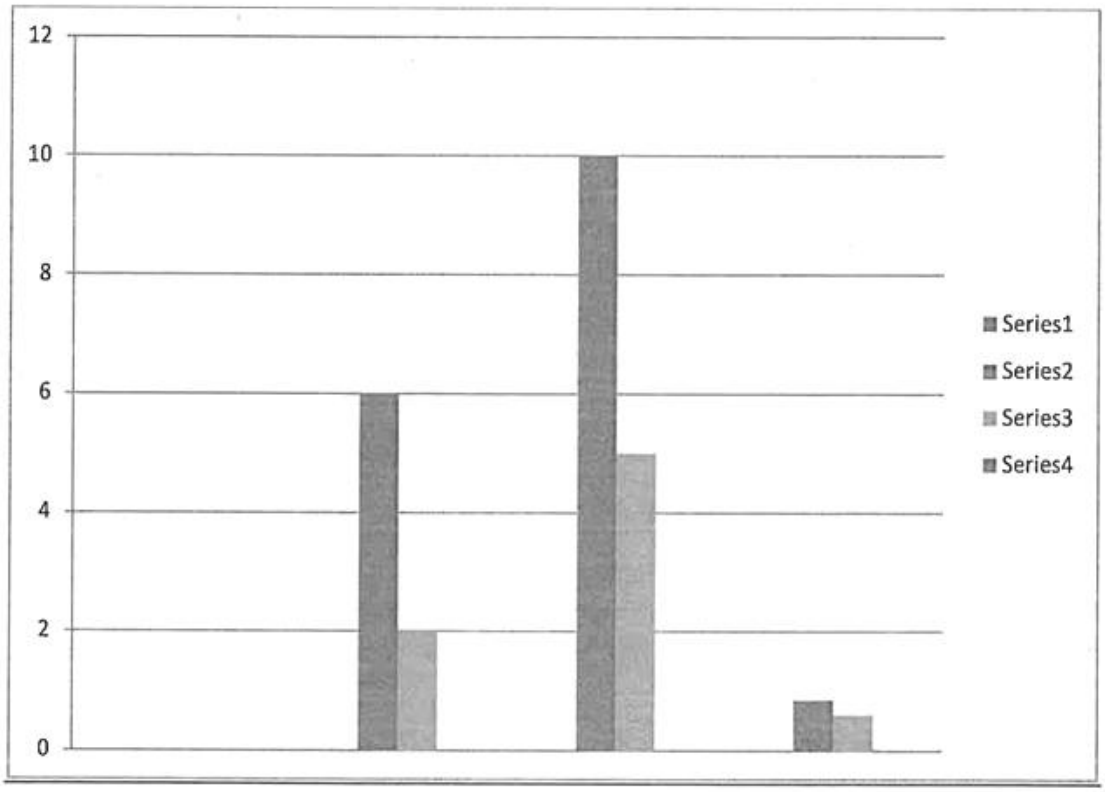


Interpretation

In total, 14 patients belonging to age group 25-40 years and 6 patients belonging to age group 41-60 years respectively had been taken for study.

TABLE – 4; Reduction of *High LDL cholesterol level in blood* in One month (20)

Age group	Reduction in symptoms 2 weeks , 4 weeks.		% of Improvement
21-45	6	10	85 %
45-60	2	5	60 %

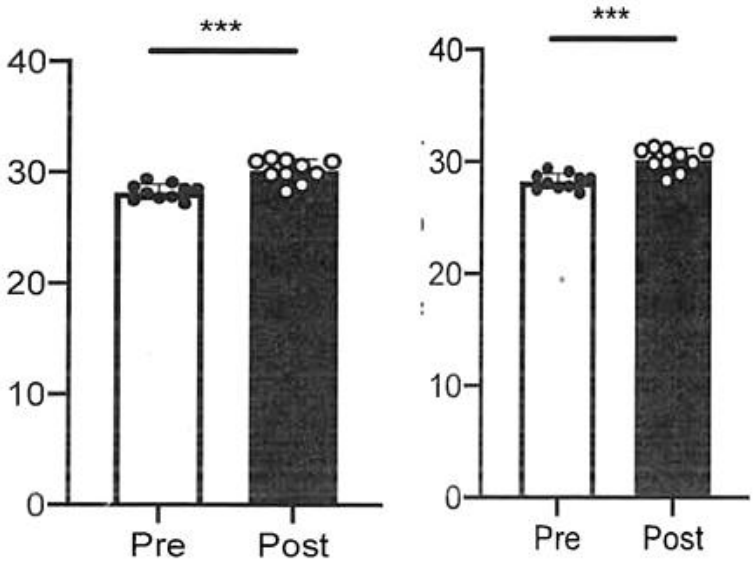


Interpretation

After the treatment of 30 days, 85% belonging to age group 25-40 years and 60% belonging to age group 41-60 years respectively had significant improvement of clinical symptoms.

IMPROVEMENT IN LABORATORY FINDINGS

PRE TREATMENT-POST TREATMENT PLOTTING DOCUMENTATION FOR STATISTICAL ANALYSIS



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PRE TREATMENT-POST TREATMENT PLOTTING DOCUMENTATION FOR STATISTICAL ANALYSIS

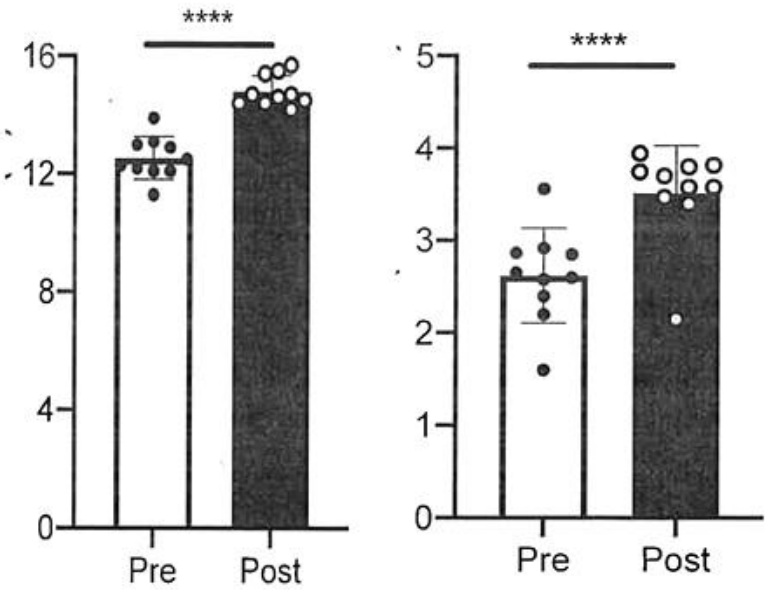
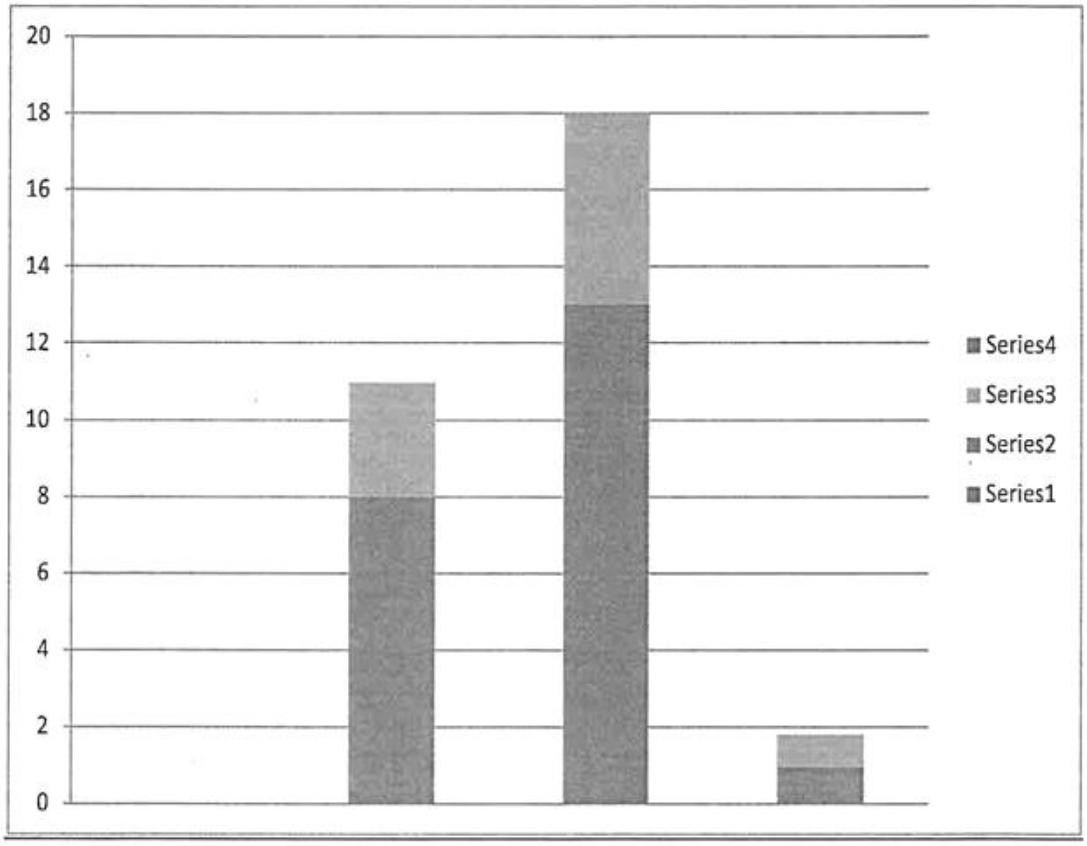


TABLE – 5; Improvement of *Athisthoolaroga (excess weight)* in One month (20)

Age group	Improvement in symptoms 2 weeks , 4 weeks.		% of Improvement
21-45	8	13	95 %
45-60	3	5	85 %

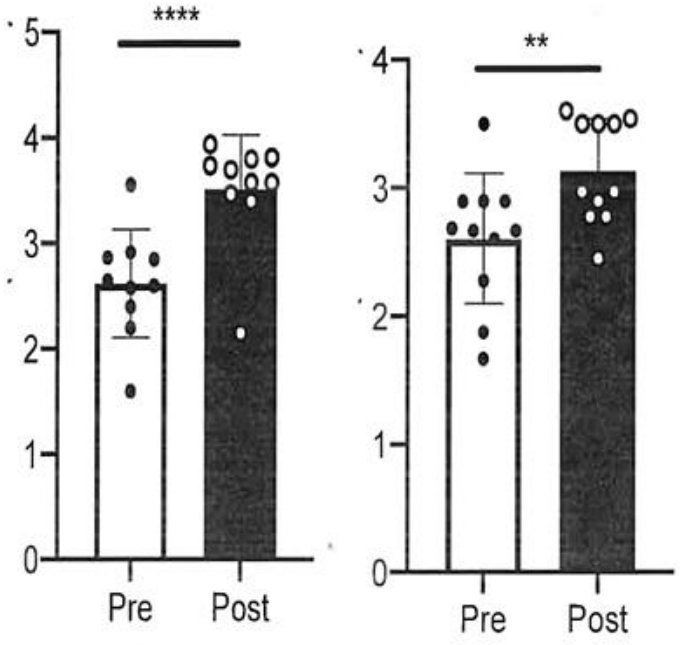


Interpretation

After the treatment of 30 days, 95% belonging to age group 25-40 years and 85% belonging to age group 41-60 years respectively had significant improvement of clinical symptoms.

IMPROVEMENT IN LABORATORY FINDINGS

PRE TREATMENT-POST TREATMENT PLOTTING DOCUMENTATION FOR STATISTICAL ANALYSIS



IMPROVEMENT IN LABORATORY FINDINGS

PRE TREATMENT-POST TREATMENT PLOTTING DOCUMENTATION FOR STATISTICAL ANALYSIS

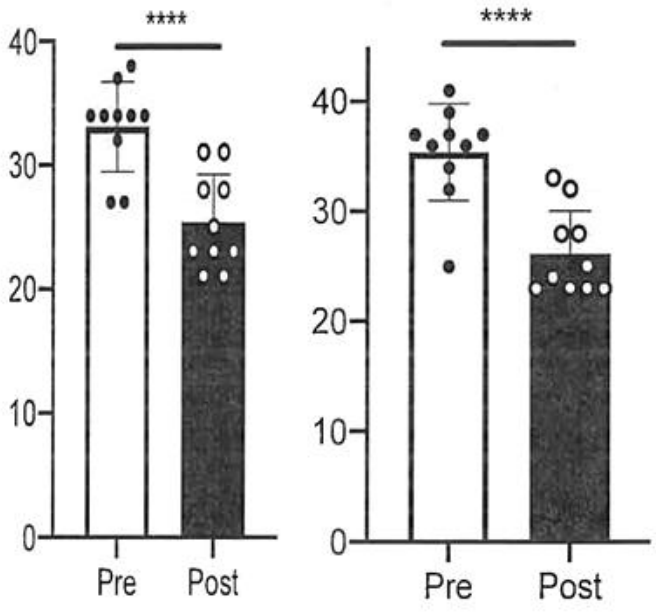
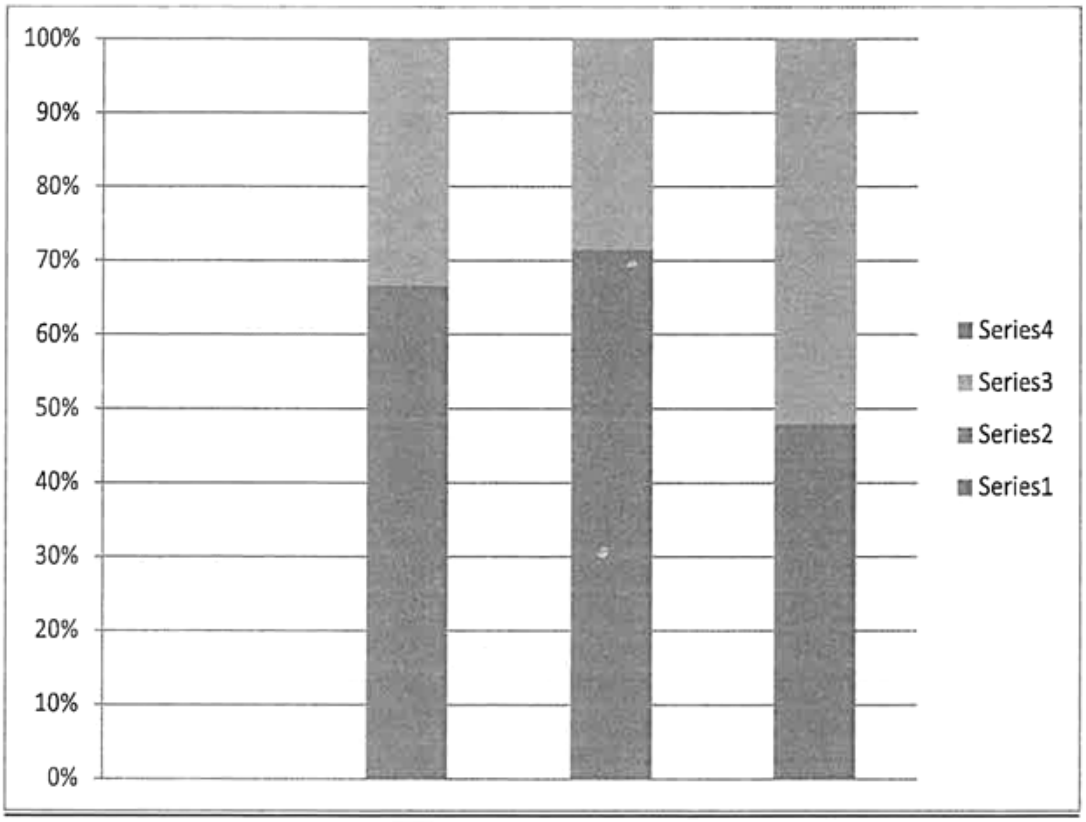


TABLE – 6; Overall Improvement of the Patient-clinically, in One month (20)

Age group	Improvement in symptoms 2 weeks , 4 weeks.		% of Improvement
21-45	6	10	60 %
45-60	3	4	65 %

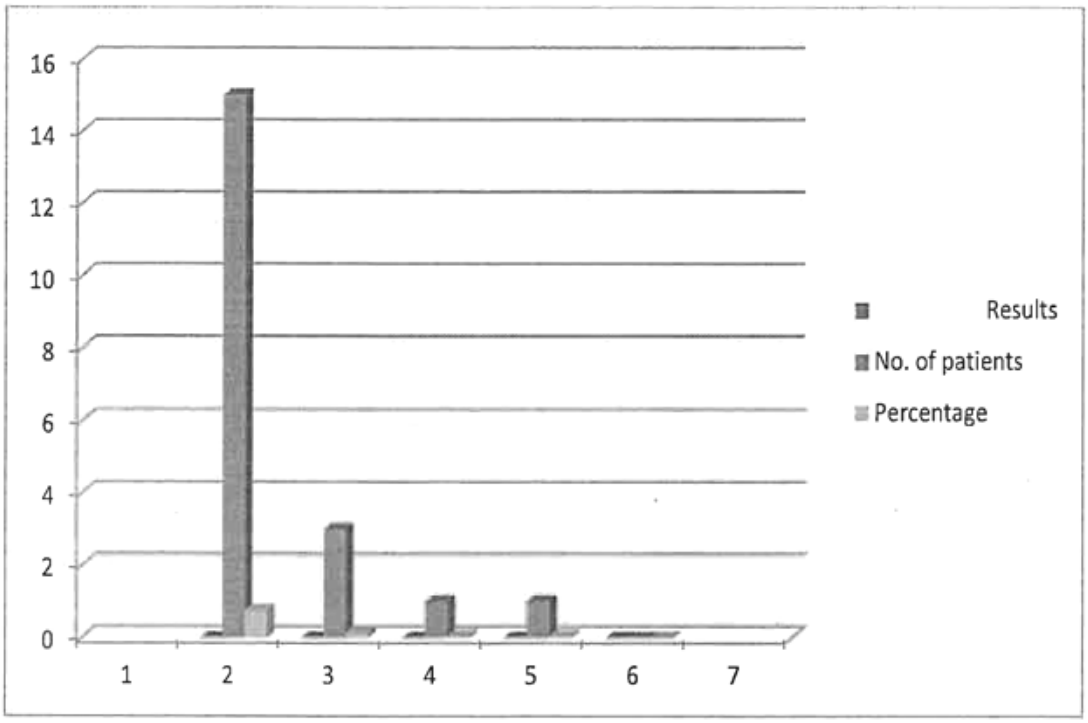


Interpretation

After the treatment of 30 days, 60% belonging to age group 25-40 years and 65% belonging to age group 41-60 years respectively had significant improvement of clinical symptoms.

Table – 7: Overall results of Treatment in reduction of Clinical symptoms and Laboratory investigations in Patients treated (Total 20 patients)

Results	No. of patients	Percentage
Very good improvement of all symptoms	15	75 %
Moderate improvement	03	15 %
Mild improvement	01	05 %
Drop out	01	05 %



Interpretation

After the treatment of 30 days, 15 patients (75%) had very good improvement of symptoms, 3 patients (15%) had moderate improvement, 1 patient (5%) had mild improvement and 1 patient (5%) had dropped out from the study.

Direct access to source data/documents

We hereby agree that the investigator(s)/institution will permit trial-related monitoring, audits, institutional review board/independent ethics committee review, and regulatory inspection(s), by the Research Council/Department of AYUSH providing direct access to source data/documents.

Quality control and quality assurance

The Manufacturing Unit of the drug is responsible for the hygienic packaging of the dose of the herbal product to be dispensed to the participant. The label should necessarily contain the word “For Clinical studies only”.

Compensation to the Participant

As per GCP guidelines the subjects were compensated for the inconvenience and time present in connection with their participation in this clinical trial, by signing a Voucher after payment of compensation.

Participant protections and ethics

To protect human participants, the protocol was written according to general ethical guidelines, such as the Declaration of Helsinki and Good Clinical Practice and was approved by the institutional ethical committee of the organization. The study participant consent process includes information about potential risks, benefits, alternatives, and responsibilities during the trial.

Before participants agree to participate in this trial, researchers will explain this information in detail in person.

Data and safety monitoring

Regular monitoring that will be clarified in a standard operating procedure will be conducted toensure good data quality. Monitors from IEC will evaluate whether the case report forms areproperly written and whether the recruiting and treatment procedures are adequatelyperformed according to the protocol. Investigators will be contacted to discuss whether it is necessary torevise the study protocol or inclusion criteria and other important issues. The investigators andindependent researchers will assess the progress of the clinical trial and severeadverse events and determine whether they are acceptable and whether it will be necessary for the trial to be modified or stopped.

Case Sheets prepared for each patient and all the records and vouchers will be retained with the treatment centre for Three years.

CONCLUSION:

Phase-II-A, Single center, Open label, Therapeutic exploratory clinical validation The current Phase-II-A, Single center, Single center, Open label, Therapeutic exploratory clinical trialsis designed to evaluate the efficacy of Proprietary Ayurvedic Medicine-DELIPOCAPSULE, Manufactured by VIJAYANI NUTRACEUTICALS PW LTD, No.2B/1,2B/2, 6th street,3rd Main road, Ambattur Industrial estate South, Ambattur, Chennai-600058. Tamil Nadu., onpatients suffering from clinical symptoms of “Shortness of breath, Fatigue, Excessive sweating, Difficulty in sleeping, High LDL cholesterol level in blood, found in Athisthoolaroga (excess weightJ, Sthoulyaroha (Obesity) and Medhoroha (Hypercholesteremia)” etc.

By consolidating the results obtained in the clinical investigations and laboratory investigations, it is hereby concluded that the Proprietary Ayurvedic Medicine- DELIPO CAPSULE, is highly effective in controlling Clinical symptoms of "Shortness of breath, Fatigue, Excessive sweating, Difficulty in sleeping, High LDL cholesterol level in blood, found in Athisthoolaroga {excess weight), Sthoulyaroha (Obesity and Medhoroha (Hypercholesteremia)" etc. It also contributed for Positive weight management at baseline and at the completion of treatment, in the recruited patients.

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