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Original Article

Efficacy and Safety of Lasunairandadi Kashayam, an Ayurvedic Formulation, as Adjunctive Therapy in Patients with Coronary Artery Disease: A Randomized Clinical Trial

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ABSTRACT

Background: Coronary Artery Disease (CAD) is the leading global cause of mortality, with its prevalence rising alarmingly in developing countries. While conventional treatments have limitations, traditional medicines like the Ayurvedic formulation Lasunairandadi Kashayam (decoction), historically used for cardiovascular conditions, necessitate rigorous scientific validation to confirm their efficacy and safety. The present study aimed to evaluate the use of that formulation as an adjunct therapy for CAD patients.

Methods: This randomized clinical trial involved 53 patients diagnosed with CAD, aged 25 to 60 years. Participants were randomly assigned to an intervention group (Lasunairandadi Kashayam plus the standard CAD treatment, n = 26) or a control group (the standard CAD treatment alone, n = 27). The intervention group received a daily dose of Lasunairandadi Kashayam for 90 days (32 mL thrice a day before meals). Primary endpoints assessed included improvements in treadmill test (TMT) scores, dyspnea on exertion, chest heaviness, chest pain, overall cardiovascular health, and lipid profiles.

Results: The intervention group showed statistically significant ameliorations in key CAD parameters compared with the standard therapy group. Notable enhancements were observed in TMT scores (from −7.0 ± 5.5 before treatment to +4.41 ± 5.2 after treatment), dyspnea on exertion, chest heaviness, chest pain, and overall cardiovascular health. Significant reductions were recorded in low-density lipoprotein-cholesterol (from 102.63 ± 29.94 before treatment to 89.50 ± 17.56 after treatment) and triglycerides (from 169.09 ± 63.79 before treatment to 145.59 ± 29.34 after treatment) in the intervention group. The safety profile was favorable, with no serious adverse effects reported.

Conclusions: Lasunairandadi Kashayam, as an adjunctive therapy to standard CAD treatment, recorded promising results in improving clinical outcomes for CAD patients. This study contributes valuable evidence toward integrating Ayurvedic interventions into mainstream cardiovascular care. ***(Iranian Heart Journal 2025; 26(1): 35-53)***

KEYWORDS: Ameliorations, Diseased vessels, Lasunairandadi Kashayam, Efficacy, Safety

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Coronary artery disease (CAD) remains a principal cause of morbidity and mortality globally. As a critical component of cardiovascular diseases, CAD contributes significantly to the high number of cardiovascular-related deaths worldwide (Brown et al, 2023). This condition is characterized by the narrowing or blockage of coronary arteries due to plaque accumulation, comprising cholesterol, lipids, and other substances. Such arterial obstruction reduces myocardial blood flow, potentially resulting in angina or myocardial infarction (Khalid et al, 2021). Risk factors such as hypertension, hyperlipidemia, smoking, diabetes, and obesity are pivotal in the onset and progression of CAD (Hajar, 2017). Annually, CAD is responsible for over 7 million deaths globally and is anticipated to remain the leading cause of death for the next 2 decades (Tian et al, 2018). Standard pharmacological treatments for CAD include β-blockers, calcium channel blockers, nitrates, angiotensin-converting enzyme (ACE) inhibitors, statins, and antiplatelet agents (Doenst et al, 2022). The prevalence of CAD can vary significantly from one region to another. High-income countries often experience higher rates of CAD, but the disease is also a growing concern in many middle- and low-income countries as lifestyles and diets change (Sreeniwas Kumar & Sinha, 2020). The situation in low-income Asian countries is comparable to, if not worse than, that in Western nations (Liang and Gu, 2021). Many Asian countries are facing significant challenges related to CAD, with mortality rates ranging from 103 to 366 per 100,000 adults (Liang and Gu, 2021).

The search for safe and effective drugs derived from natural products is a prominent area of research in the field of CAD (Slovinski et al, 2019). Medicinal plants offer significant advantages in the treatment of cardiovascular diseases due to their favorable safety profiles (Hao & Xiao, 2019). These plants have shown beneficial effects in managing conditions such as hypertension, hyperlipidemia, atherosclerosis, and chronic heart failure, as well as in reducing overall cardiovascular risk (Hao & Zhang, 2019). Educating cardiovascular disease patients about the advantages of medicinal plants could lead to improved health outcomes. For instance, incorporating medicinal plants into the diet may effectively help control hypertension (Diab et al, 2023).

Natural products and herbal remedies have garnered substantial research attention for the prevention and treatment of cardiovascular diseases (Waltenberger et al, 2016). This interest is driven by several factors, including the potential for cost-effective treatments compared with conventional therapies and the widespread belief in their safety and efficacy. Consequently, numerous medicinal plants have been employed in managing cardiovascular conditions. Recently, traditional herbal medicines have become crucial in health maintenance, disease prevention and treatment, and the discovery of plant-based drugs (Yuan et al, 2016). Ayurveda, a traditional system of medicine practiced in India for thousands of years, exemplifies the significant role of these remedies. In the Ayurvedic tradition, cardiovascular health is recognized as integral to overall well-being, and traditional Ayurvedic therapies are designed to harmonize the doshas (Vata, Pitta, and Kapha) to support optimal heart function. Ayurveda adopts a holistic perspective on health and well-being, emphasizing the equilibrium of the mind, body, and spirit. Ayurvedic treatments for CAD often involve lifestyle modifications, dietary changes, and the use of various herbs and formulations (Nishteswar, 2014). It is important to note that while some people find Ayurvedic practices beneficial, the scientific evidence supporting the efficacy of Ayurvedic treatments for CAD is limited, and more

research, especially in the area of clinical research, is needed.

Lasunairandadi Kashayam is an Ayurvedic herbal decoction or medicinal liquid preparation. Lasunairandadi Kashayam is named after one of its principal ingredients, "Lasuna," which refers to garlic (*Allium sativum*). Lasunairandadi Kashayam is traditionally used in Ayurveda for conditions related to the respiratory system, digestion, and cardiovascular health. The inclusion of garlic suggests that it may be used for its potential benefits in maintaining heart health, including managing cholesterol levels and supporting overall cardiovascular function. Lasunairandadi Kashayam consists of 6 herbal medicines (Table 1): *Allium sativum*, *Ricinus cummunis*, *Caesalpinia bonduc*, *Boerhavia diffusa*, *Sphaeranthus indicus*, and *Zingiber officinale*. Among these natural remedies, *Allium sativum* stands out as a principal source of pharmacologically active compounds. Its constituents demonstrate a variety of pharmacological effects, including antioxidative, anti-atherosclerotic, lipid-lowering, antiplatelet aggregation, vascular endothelial cell-protective, and anti-inflammatory properties, among others (Ramachandran et al, 2010; Salih et al, 2023; Marx et al, 2015; Hiyasat et al, 2009; Sobenin et al, 2016; Bordia et al, 1998; Kamanna & Chandrasekhara, 1982; Olaleye et al, 2010; Pari & Amarnath, 2004; Doenst et al, 2022). Currently, there is a lack of scientific evidence regarding the efficacy of Lasunairandadi Kashayam in the treatment of CAD within the existing literature. However, we have previously published a single case report detailing the potential effectiveness of Lasunairandadi Kashayam in managing CAD (Kasthuri et al, 2019). The utilization of herbal medicine as an adjunct or supplementary therapy in CAD remains an area of interest. It is vital to note that while some herbal remedies have been traditionally used and are studied for their potential cardiovascular benefits, evidence supporting their efficacy and safety may vary. Therefore, the current investigation was designed as a randomized clinical study aiming to evaluate the effectiveness and safety of Lasunairandadi Kashayam as an add-on therapy for the treatment of CAD patients.

Table 1: Herbal Ingredients Used for Preparing Lasunairandadi Kashayam

S. No.	Sanskrit Name	Botanical Name	Form Used
1	Lasuna	*Allium sativum*	Bulb
2	Eranda	*Ricinus cummunis*	Root
3	Yakshakshi	*Caesalpinia bonduc*	Root
4	Varshabhu	*Boerhaavia diffusa*	Root
5	Hapusha	*Sphaeranthus indicus*	Root
6	Aushadha	*Zingiber officinale*	Rhizome

METHODS

The major aim of this trial was to evaluate the efficacy and safety of Lasunairandadi Kashayam when used as an adjunctive therapy for the management of CAD in adults aged between 25 and 60 years.

Study drug

Lasunairandadi Kashayam utilized in this study was manufactured in accordance with Good Manufacturing Practices (GMP) standards at the production facility of Pankajakasthuri Herbals India Pvt Ltd, located in Poovachal, Thiruvananthapuram, Kerala, India. Detailed information regarding the ingredients employed in the preparation of Lasunairandadi Kashayam is provided in Table 1.

Preparation of the study drug

The dried roots of *R. cummunis*, *C. bonduc*, *B. diffusa*, *S. indicus*, *A. sativum* bulb, *Z. officinale* rhizome, and Hingu (*Ferula asafoetida*) were obtained from authorized dealers, meticulously cleaned following standard purification procedures, and thoroughly dried and powdered individually. Drugs 1 to 6 were combined in equal

proportions and blended into a coarse powder, which was then packed into 48 g packets. *F. asafoetida* was separately processed by frying in cow ghee, followed by drying, powdering, and packing into 150 mg packets.

Each day, one 48 g pack of Lasunairandadi dried powder, combined with 150 mg of *F. asafoetida*, was utilized to prepare the required decoction. Patients were provided with a 90-day supply, comprising 90 packs of Lasunairandadi Kashayam. They were instructed to place the herbal pack into a pot, add 768 mL of water, and simmer the mixture over low heat until the volume was reduced to 96 mL. The standardized preparation process was demonstrated to patients allocated to the study drug arm (interventional) at the Department of Rasashastra and Bhaishajya Kalpana of Pankajakasthuri Ayurveda Medical College Hospital and PG Center, Kattakada, Thiruvananthapuram, Kerala, India, via a video presentation. Patients were advised to consume a daily dosage of 32 mL thrice a day, before meals.

Ethics committee approval

The study protocol adhered to the ethical standards delineated in the Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects. Approval for the study protocol was obtained from the Ethics Committee of Pankajakasthuri Ayurveda Medical College Hospital and PG Center, as evidenced by approval number PKAMC/ADM/01/2017. Before commencement, informed consent was obtained from all participating subjects following a comprehensive explanation of the study's objectives, procedures, and potential risks and benefits.

Study subjects

From May 2018 through April 2019, 53 patients of either sex diagnosed with CAD in the age group between 25 and 60 years were included in the study from the outpatient and inpatient departments of Kayachikitsa (General Medicine), Pankajakasthuri Ayurveda Medical College Hospital and PG Center, Killy, Kattakada, Thiruvananthapuram, Kerala, India.

Inclusion criteria

Patients were included in the study if they met the following criteria: 1) subjects diagnosed as having CAD according to the treadmill test (TMT) report and ECG; 2) subjects between the ages of 25 and 60; 3) subjects of either sex, irrespective of socioeconomic status; 4) subjects who were willing to provide written informed consent; and 5) subjects on antiplatelet with or without cholesterol-modifying drugs and β-blockers.

Exclusion criteria

The following are the exclusion criteria included in the present investigation: 1) subjects with coronary artery stents; 2) subjects on heparin; 3) subjects diagnosed with renal, respiratory, neurologic, immunologic, and infectious diseases; 4) subjects diagnosed with any other congenital cardiac issues or those post-myocardial infarction; 6) women who were pregnant, breastfeeding, or planning to become pregnant during the study; and 6) subjects with uncontrolled diabetes mellitus and hypertension.

Randomization and interventions

Based on the specified inclusion and exclusion criteria, patients were randomized into 2 groups: an intervention group (Lasunairandadi Kashayam) comprising 26 patients, and a standard therapy group composed of 27 patients. The standard therapy group received only the standard CAD medications previously prescribed by their physicians, including antiplatelets, statins, β-blockers, ACE inhibitors, nitrates, calcium channel blockers, and anticoagulants. In addition to these standard

medications, patients in the intervention group received Lasunairandadi Kashayam. Participants were instructed to maintain their routine medical treatments, dietary habits, and lifestyle throughout the study period. No new medications were introduced for any subjects during the study.

All treatments were administered by physicians following clinical guidelines. The study medications, including both standard CAD medicines and Lasunairandadi Kashayam, were dispensed by the Hospital Central Pharmacy in a set of boxes at the beginning of the study. To monitor patient compliance, we instructed all patients to return the boxes. Treatment prescriptions and patient conditions were documented in the Case Report Form.

Baseline assessment

Patient demographic details, pre-existing health conditions, vital signs, lipid profiles, and blood sugar were recorded at baseline.

Assessment of the study outcomes

Primary outcomes

Change in major adverse cardiovascular events, including the TMT, dyspnea on exertion (DOE), chest heaviness, chest pain, palpitations, gastric discomfort, pedal edema, sweating, and lipid profiles (total cholesterol, triglycerides, low-density lipoprotein, high-density lipoprotein, and very low-density lipoprotein) were assessed as the primary endpoints. The supplementary file shows more details on the grading scale of DOE, chest heaviness, chest pain, palpitations, gastric discomfort, pedal edema, and sweating. Primary endpoint analysis was performed at the screening visit (day 0) (before treatment [BT]), day 91 (after treatment [AT]), and the final visit (day 120) (after follow-up [AF]) except for lipid profiles. Lipid profiles were assessed on the screening visit (day 0) and day 91.

Secondary outcomes

Secondary endpoints included adverse events and changes in fasting blood sugar, postprandial blood sugar, liver profile (aspartate transaminase, alanine transaminase, alkaline phosphatase, total protein, and total bilirubin), and renal profile (serum creatinine, urea, uric acid, sodium, and potassium). All routine clinical chemistry parameters were analyzed using the Erba Chem 5 Plus V2 analyzer (ERBA Diagnostics Mannheim GmbH, Mannheim, Germany). Secondary endpoints were assessed at the screening visit (day 0) and on day 91. Physical examinations, demographics (height, weight, and body mass index), and vital signs were evaluated at each visit.

Periodic assessments were conducted at the screening visit (day 0), visit 1 (day 15), visit 2 (day 30), visit 3 (day 45), visit 4 (day 60), visit 5 (day 75), and the final visit (day 91).

Termination of the clinical trial

Patients retained the right to withdraw their consent to participate in this study at any time, without penalty or impact on their medical care or loss of benefits. They were asked to inform the investigator promptly upon deciding to withdraw their consent.

Adverse event management

Any unexpected symptoms, changes in vital signs, or illnesses causing discomfort were documented as adverse events. Details including the onset and resolution dates, severity, relationship with the trial medication, and whether patients discontinued the study were recorded. Severe adverse events necessitated immediate reporting to the lead researcher and ethics committees within 24 hours, with patients receiving appropriate treatment. Follow-up continued until resolution if adverse events persisted.

Statistical Analysis

Descriptive statistics, such as frequencies, means, and standard deviations, were used to present the data. Statistical comparisons of primary characteristics and outcomes between the treatment and standard therapy groups were conducted using the analysis of variance (ANOVA) and the Wilcoxon signed-rank test. An intention-to-treat analysis protocol was employed to analyze data from patients who did not fully adhere to the study protocol. A significance level of $P < 0.05$ was applied. Data analysis was performed using SPSS software (version 17, IBM Corp).

RESULTS

Out of 58 patients assessed for eligibility, 5 patients were excluded from the investigation. Hence, 53 patients with CAD were selected for randomization in the interventional and standard therapy groups. Of the 53 patients, 81.8% were men, and the mean age was 54.9 years. After the screening, patients were randomized into 2 groups: interventional and standard therapy. The patients in the interventional group (n = 26) received standard therapy along with Lasunairandadi Kashayam, whereas the patients in the standard therapy group (n = 27) received only standard therapy. During the progress of the study, 4 subjects from the interventional group and 5 subjects from the standard therapy group were excluded from the study due to immigration, uncontrolled diabetes, required surgery, or refusal to continue the study. Thus, the intervention was completed in 22 patients in each group. No difference in the adjustment of dose or new use of drugs in the standard therapy was implemented. Patients continued the same treatment of standard CAD therapy prescribed earlier by physicians (Table 2). The baseline characteristics of all eligible patients from the 2 treatment groups were listed and compared. No significant differences were observed between the 2 groups concerning age, sex, body mass index, smoking, and blood pressure.

Table 2: The Baseline Characteristics of the Patients in the Interventional and Standard Therapy Groups

Characteristics	Interventional Group (n=22)	Standard Therapy Group (n=22)
Sex male female	 81.8% 18.2%	 81.8% 18.2%
Mean (SD) age, y	54.72±4.71	50.9±5.41
Mean (SD) weight, kg	69.41±14.24	77.23±15.39
Mean (SD) height, cm	161.8±9.87	165.68±9.08
Mean (SD) body mass index	26.75±6.47	28.12±4.88
Current smokers	22.72%	8.18%
Clinical Presentations		
Stable angina	31.81%	27.27%
Unstable angina	22.72%	13.63%
Atypical chest pain	27.27%	31.81%
Silent ischemia	9.09%	4.54%
Comorbidities		
Hypertension	68.18%	59.09%
Diabetes mellitus	72.73%	81.81%
Hyperlipidemia	63.63%	50%
Standard Drugs		
Antiplatelets	90.90%	95.45%
Anticoagulants	81.81%	90.91%
Angiotensin-converting enzyme	72.73%	86.36%

Nitrates	40.90%	11 50%
β-blockers	63.63%	77.27%
Calcium channel blockers	72.72%	81.81%
Metformin	63.63%	68.18%
Statins	86.36%	81.81%
Other antidiabetics	9.09%	4.54%
Trimetazidine	22.72%	13.63%
Total cholesterol, mg/dL	176.95±24.49	189.04±29.46
High-density lipoprotein, mg/dL	51.59±11.97	47.45 ±9.87
Triglycerides, mg/dL	169.09±63.79	120.72±51.15
Very low-density lipoprotein, mg/dL	29.45±11.34	27.13±16.55
Low-density lipoprotein, mg/dL	102.63±29.94	101.72±29.36
Blood glucose, mg/dL	123.18±42.73	124.59±20.74
Systolic blood pressure	138.18±16.90206	129.77±10.51
Diastolic blood pressure	88.18±9.57	88.86±9.75

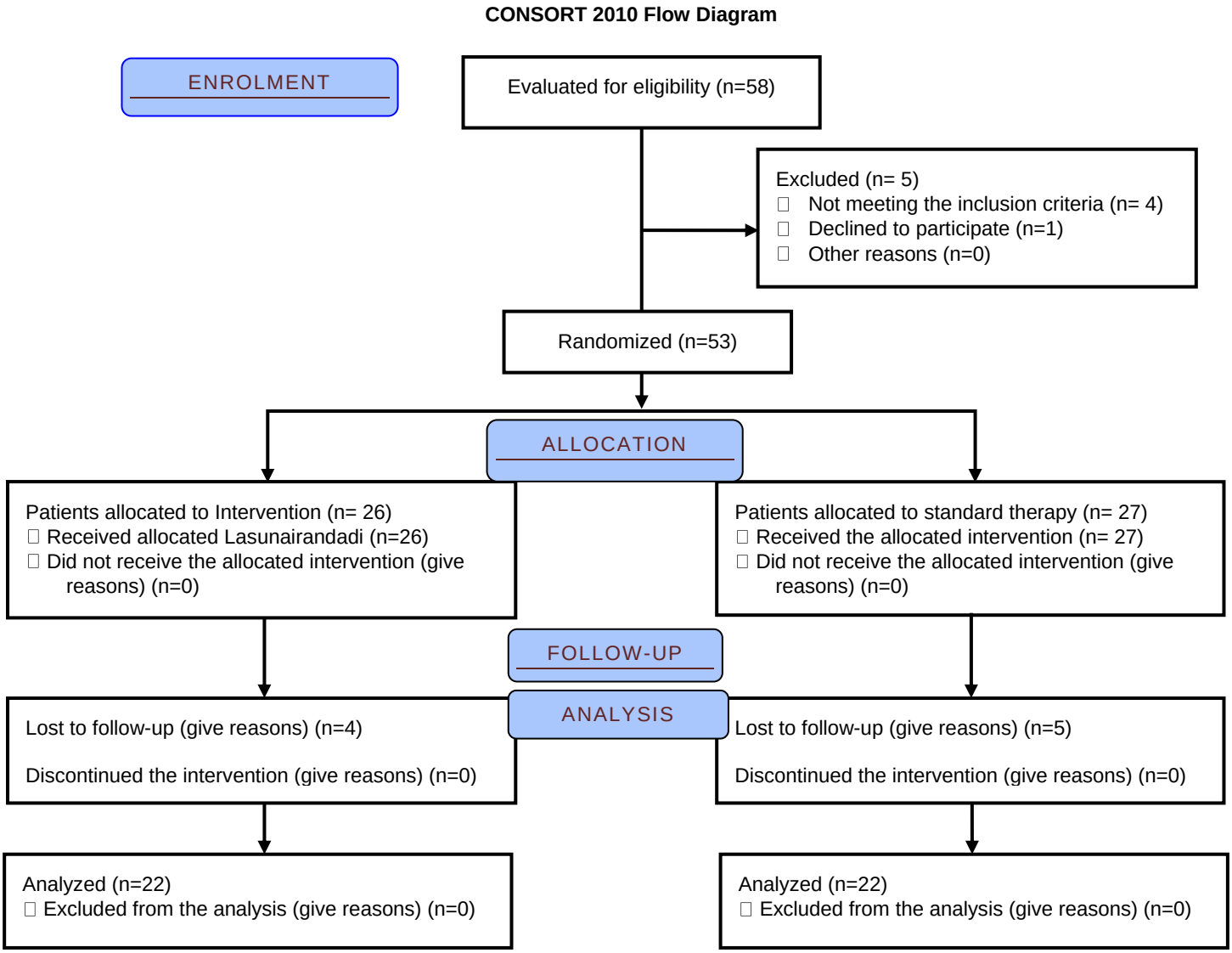

Figure 1: The image illustrates the trial flow chart of the current study.

Treatment with Lasunairandadi Kashayam significantly reduced the TMT score.

In the interventional group, the mean TMT score before treatment was −7.0 ± 5.5, which improved to +4.41 ± 5.2 post-treatment and +4.55 ± 4.7 during follow-up (Fig. 2). Conversely, in the standard therapy group, the mean TMT score before treatment was -4.95 ± 3.4, which increased to −5.82 ± 3.4 post-treatment and −6.23 ± 3.4 during follow-up. The results suggest that treatment with Lasunairandadi Kashayam significantly enhanced the average TMT score compared with the standard therapy group.

Treatment with Lasunairandadi Kashayam significantly improved CAD parameters in the patients.

DOE

The study findings revealed a marked enhancement in DOE among participants in the interventional group compared with those in the standard therapy group (Figure 3A). Statistical analysis using the Wilcoxon signed-rank test unveiled a significant reduction in DOE between BT and AT, as well as between BT and AF, in the interventional group ($P < 0.001$ for both). Nonetheless, the reduction in DOE between AT and AF exhibited a slightly less significant trend ($P = 0.083$). Conversely, in the standard therapy group, the Wilcoxon signed-rank test demonstrated highly insignificant results ($P = 0.317$) regarding DOE across BT, AT, and AF (Fig. 3A). These findings underscore the efficacy of the intervention in mitigating dyspnea symptoms and suggest its potential as a therapeutic approach for patients experiencing DOE.

Chest heaviness

The results of the present investigation demonstrated that patients in the interventional group experienced a significant reduction in chest heaviness compared with those in the standard therapy group (Fig. 3B). The Wilcoxon signed-rank test revealed a highly significant reduction in chest heaviness between BT and AT, as well as between BT and AF, in the interventional group ($P < 0.001$). Nevertheless, there was no significant difference in chest heaviness between AT and AF in the interventional group ($P = 0.317$). In contrast, the standard therapy group showed no significant changes in chest heaviness across BT, AT, and AF according to the Wilcoxon signed-rank test ($P = 0.317$).

Chest pain

The results from the present investigation demonstrated that patients in the interventional group experienced a significant improvement in chest pain compared with those in the standard therapy group after the treatment period (Fig. 3C). The Wilcoxon signed-rank test revealed a significant reduction in chest pain between BT and AT, as well as between BT and AF, in the interventional group ($P = 0.002$). Still, the difference in chest pain between AT and AF in the interventional group was not significant ($P = 0.317$). In the standard therapy group, the Wilcoxon signed-rank test showed no significant changes in chest pain between BT and AT and between AT and AF ($P = 0.317$). Additionally, the change in chest pain between BT and AF was not significant ($P = 0.083$).

Palpitations

The investigation results unequivocally demonstrated a significant improvement in palpitations among patients in the interventional group compared with those in the standard therapy group following the treatment period (Fig. 3D). The Wilcoxon signed-rank test revealed a substantial reduction ($P = 0.006$) in palpitations between BT and AT and between BT and AF and indicated no significant difference ($P = 0.317$) in palpitations between AT and

AF in the interventional group. Conversely, in the standard therapy group, the Wilcoxon signed-rank test exhibited considerably insignificant results (P = 0.317) in palpitations between BT, AT, and AF.

Gastric discomfort

The findings of the current investigation explicitly demonstrated a significant improvement in gastric discomfort among patients in the interventional group compared with those in the standard therapy group after the treatment period (Fig. 3E). The Wilcoxon signed-rank test revealed a highly significant reduction (P < 0.001) in gastric discomfort between BT and AT and between BT and AF and indicated a nonsignificant difference (P = 0.157) in gastric discomfort between AT and AF in the interventional group. Conversely, in the standard therapy group, the Wilcoxon signed-rank test showed highly insignificant results (P = 0.317) in gastric discomfort between BT and AT and between AT and AF and a nonsignificant result (P=0.157) between AT and AF.

Pedal edema

The findings from the current investigation demonstrated a significant improvement in pedal edema among patients in the interventional group compared with those in the standard therapy group after the treatment period (Fig. 3F). The Wilcoxon signed-rank test revealed a significant reduction (P < 0.001) in pedal edema between BT, AT, and AF in the interventional group. Conversely, in the standard therapy group, the Wilcoxon signed-rank test showed highly nonsignificant results (P = 0.317) in pedal edema between BT, AT, and AF.

Sweating

The findings of the present investigation indicate that patients in the interventional group exhibited a significant improvement in sweating compared with those in the standard therapy group after the treatment period (Fig. 3G). The Wilcoxon signed-rank test revealed a significant reduction (P = 0.015) in sweating between BT and AT and a nonsignificant reduction (P = 0.317) in sweating between BT and AF in the interventional group. Additionally, a significant reduction (P = 0.014) in sweating was observed between AT and AF in the interventional group. In contrast, the Wilcoxon signed-rank test showed highly insignificant results (P = 0.317) concerning sweating between BT, AT, and AF in the standard therapy group.

Lipid parameters

The lipid profiles of randomly assigned patients from both groups were subsequently evaluated (Table 3). In the interventional group, administration of Lasunairandadi Kashayam led to noteworthy reductions in triglycerides, very low-density lipoprotein, and low-density lipoprotein. Notably, comparative analyses post-treatment between the 2 groups revealed more pronounced reductions in these lipid parameters in the interventional group compared with the standard therapy group. Furthermore, fasting blood sugar and postprandial blood sugar levels exhibited significant decreases in the interventional group, whereas no significant alterations were observed in the standard therapy group pre- and post-treatment. Similarly, significant improvements in both systolic and diastolic blood pressure were noted in the interventional group (Table 3).

Safety parameters

Vital parameters in the liver and renal function tests remained stable throughout the study period in both groups. Laboratory evaluations revealed no significant changes in kidney and liver blood parameters in either group, indicating the safety of the interventions by the study's conclusion (Table 4).

Safety evaluation

No adverse events or serious adverse events were observed in either the interventional or standard therapy group during the study (Table 5). Additionally, none of the patients consumed concomitant medications throughout the study period.

Table 3: Lipid Profile Changes in the Studied Patients Before and After Treatment

Parameters	Lasunairandadi Kashayam Group (n=22)		Standard Therapy Group (n=22)	
	Before Treatment	After Treatment	Before Treatment	After Treatment
Total cholesterol, mg/dL	176.95±24.49	170.90±20.39	189.04±29.46	189.95±24.16
High-density lipoprotein, mg/dL	51.59±11.97	55.77±9.46	47.45 ±9.87	58.36±17.84
Triglycerides, mg/dL	169.09±63.79	145.59±29.34	120.72±51.15	123.13±42.14
Very low-density lipoprotein, mg/dL	29.45±11.34	24.72±7.09	27.13±16.55	26.00±7.144
Low-density lipoprotein, mg/dL	102.63±29.94	89.50±17.56	101.72±29.36	96.86±28.61
Fasting blood sugar	123.18±42.73	105.86±15.62	124.59±20.74	120.77±18.34
Postprandial blood sugar	172.31±61.01	144.22±25.03	142.18±30.26	142.13±18.39
Systolic blood pressure	138.18±16.90	127.72±9.22	129.77±10.51	131.90±14.54
Diastolic blood pressure	88.18±9.57	82.72±4.55	88.86±9.75	90.68±10.61

Values are presented as mean ± SD.

P < 0.05 compared with baseline within the same group

Table 4: Liver and Renal Function Tests in the Lasunairandadi Kashayam-Treated Group Before and After Treatment

Parameters	Lasunairandadi Kashayam Group (n=22)		Standard Therapy Group (n=22)	
	Before Treatment	After Treatment	Before Treatment	After Treatment
Liver Function Test				
Aspartate transaminase	24.30±13.13	21.91±6.54	16.91±6.45	19.52±4.05
Alanine aminotransferase	33.70±20.46	19.08±5.61	29.04±9.41	26.65±9.57
Alkaline phosphatase	78.26±18.2	67.17±22.8	80.48±24.2	77.83±29.1
Total bilirubin	0.6±0.32	0.74±0.31	0.65±0.19	0.56±0.23
Total protein	7.12±0.75	7.21±0.79	7.10±0.32	7.36±0.41
Renal Function Test				
Urea	24.86±7.67	30.78±9.25	23.08±6.62	23.65±5.98
Creatinine	0.78±0.22	0.86±0.25	0.74±0.19	0.80±0.19
Uric acid	4.55±1.47	5.16±1.40	4.05±0.99	5.21±1.20
Sodium	137.65±5.82	138.86±3.27	139.15±3.18	138.60±1.90
Potassium	4.54±0.37	4.50±0.46	4.51±0.30	4.34±0.27

Values are presented as mean ± SD.

P < 0.05 compared with baseline within the same group

Table 5: Assessment of Adverse Side Effects

Parameters	Interventional Group	Standard Therapy Group
Nausea	1	2
Vomiting	Nil	1
Headache	2	2
Drowsiness	Nil	Nil
Rashes	Nil	Nil
Fatigue	1	2
Dizziness	Nil	1
Tremors	Nil	Nil

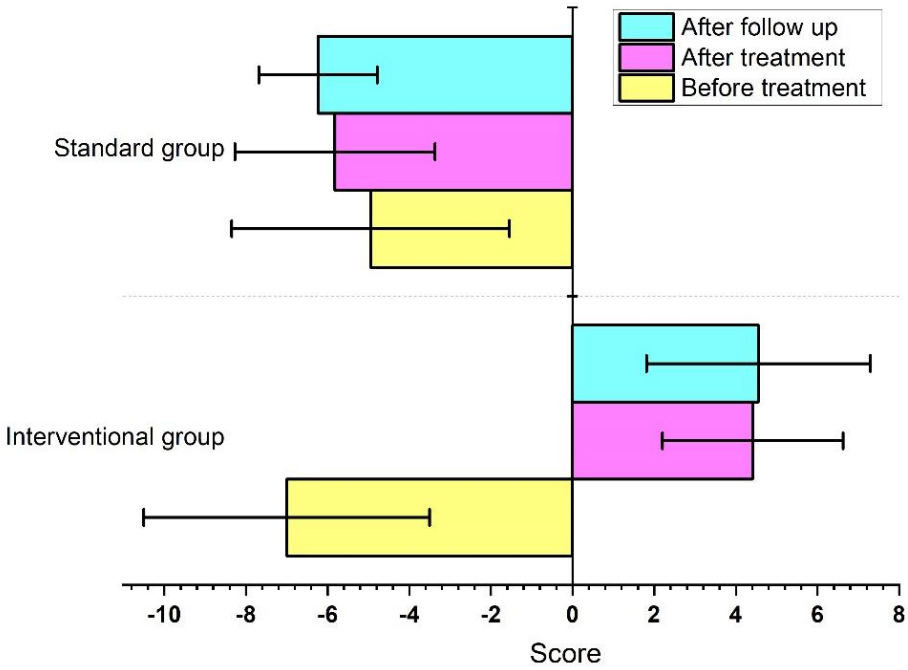

Figure 2: The image provides the treadmill test scores of the subjects in the interventional and standard therapy groups.

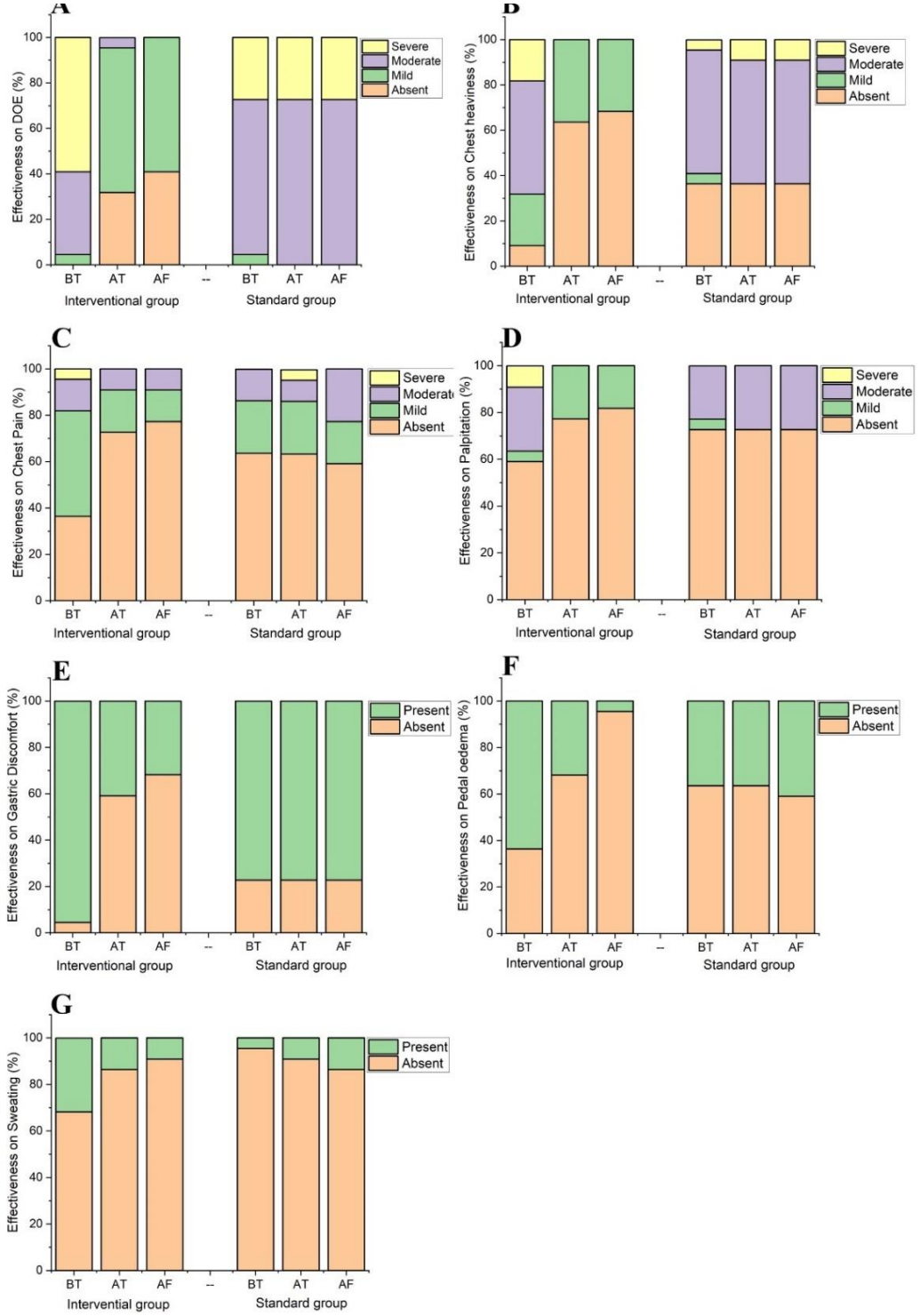

Figure 3: Treatment with Lasunairandadi Kashayam significantly improved overall CAD parameters. [A] dyspnea on exertion, [B] chest heaviness, [C] chest pain, [D] palpitations, [E] gastric discomfort, [F] pedal edema, and [G] sweating.

CAD: coronary artery disease, BT: before treatment, AT: after treatment, AF: after follow-up

DISCUSSION

In recent years, various factors, including an aging population, have contributed to a sharp increase in cardiovascular diseases (Liang & Gu, 2021). Mortality from cardiovascular diseases is also rising rapidly worldwide, posing a significant threat to global health (Liang & Gu, 2021). CAD is among the most prevalent types of cardiovascular diseases, accounting for over 9.5 million deaths globally (Zhu et al, 2016). Although preventive and therapeutic interventions have markedly improved the prognosis of CAD over the past 3 decades, the incidence of cardiovascular events remains high, particularly among high-risk patients with multiple risk factors such as hypertension, hyperlipidemia, and diabetes mellitus. This trend has persisted despite the widespread use of conventional treatments, including aspirin, statins, and β-blockers (Naghavi, 2017; Hajar, 2017). CAD is also a major contributor to healthcare costs due to the expenses associated with diagnosis, treatment, and long-term management. These costs involve hospitalizations, medications, surgeries, and rehabilitation (Bauersachs et al, 2019). Accordingly, there is an urgent need to develop alternative therapies for managing CAD effectively. Therefore, the current investigation aimed to evaluate the effectiveness and safety of Lasunairandadi Kashayam, a traditional medicine as an add-on therapy for the treatment of CAD patients.

Lasunairandadi Kashayam is traditionally used in Ayurveda for conditions related to the respiratory system, digestion, and cardiovascular health. Lasunairandadi Kashayam consists of 6 herbal medicines: *A. sativum*, *R. cummunis*, *C. bonduc*, *B. diffusa*, *S. indicus,* and *Z. officinale*. The inclusion of *A. sativum* suggests that it may be used for its potential benefits in maintaining heart health by managing cholesterol levels and supporting overall cardiovascular function (Li et al, 2022). While these individual herbs have been studied for potential cardiovascular benefits, it is imperative to note that the evidence supporting the efficacy and safety of Lasunairandadi Kashayam as a whole is inadequate, and more investigation is needed. In this study, patients with CAD were randomized into 2 groups: interventional and standard therapy. The interventional group received Lasunairandadi Kashayam, along with standard CAD medicines, whereas the standard therapy group received only standard CAD medicines. After the investigation period (90 days), the efficacy of Lasunairandadi Kashayam in improving the CAD parameters was accessed by investigating the TMT score, DOE, chest heaviness, chest pain, palpitations, gastric discomfort, pedal edema, sweating, and lipid profiles.

The TMT, also known as an exercise stress test or stress ECG, is a diagnostic test commonly used to evaluate the heart's response to physical stress, particularly in the context of CAD (Rahsepar et al, 2015). The TMT is primarily used to detect myocardial ischemia, a condition where the blood supply to the heart muscle is inadequate during physical stress. In CAD, narrowed or blocked coronary arteries can limit blood flow to the heart, especially during periods of increased demand, such as exercise (Bruning & Sturek, 2015). The TMT helps identify abnormal changes in the ECG that may suggest insufficient blood flow. Further, the TMT allows the observation of the patient's response to physical stress, including the development of symptoms such as chest pain and discomfort (Vilcant & Zeltser, 2021). The occurrence of symptoms during the test can provide important information about the presence and severity of CAD (Vilcant & Zeltser, 2021). The TMT can also be drawn upon to monitor the effectiveness of

interventions for CAD, such as medications or revascularization procedures. Changes in TMT results over time may indicate improvements or exacerbation of the underlying CAD (Vilcant & Zeltser, 2021). To enhance the sensitivity and specificity of exercise ECG tests, researchers have developed various scoring systems. One widely validated index is the Duke Treadmill Score (DTS), which is employed to improve the diagnostic accuracy of exercise ECG tests (Shaw et al, 1998). Hence, in the present investigation, the TMT was used to assess the efficacy of Lasunairandadi Kashayam in improving CAD after the treatment period. Our results demonstrated that Lasunairandadi Kashayam, when used as an add-on therapy, significantly improved the TMT score, indicating an improvement in CAD.

DOE, also known as shortness of breath during physical activity, can be a symptom of CAD (Burki & Lee, 2010). In CAD, coronary arteries, which supply the heart muscle with oxygen and nutrients, become narrowed or blocked due to atherosclerosis. This narrowing can result in an inadequate blood supply to the heart, particularly during periods of increased demand, such as physical exertion. This mismatch between the heart's oxygen demand and the restricted blood flow can lead to symptoms such as DOE. The severity of symptoms can vary depending on the degree of blockage in the coronary arteries (Berliner et al, 2016). In our investigation, the Lasunairandadi Kashayam-administered group recorded a significant improvement in the DOE compared with the standard therapy group. Consequently, it can be suggested that the ingredients present in Lasunairandadi Kashayam aid in removing atherosclerosis, which may lead to an improvement in DOE. Chest heaviness or discomfort is a common symptom associated with CAD (Haasenritter et al, 2012). CAD is characterized by the narrowing or blockage of coronary arteries, which supply the heart muscle with oxygen and nutrients. Chest heaviness is often a result of inadequate blood flow to a portion of the heart muscle, typically during periods of increased demand or stress. This symptom is commonly known as angina pectoris (Huffman et al, 2002). Chest pain is a hallmark symptom of CAD, and it can indicate a range of conditions within this spectrum (Montero-Pérez et al, 2017). The most common cause of chest pain related to CAD is angina pectoris. In CAD, coronary arteries become narrowed or blocked, resulting in reduced blood flow to the heart muscle. This can result in various symptoms, including palpitations. When the heart muscle does not receive an adequate blood supply, it may respond with irregular heartbeats or other arrhythmias (Andrikopoulos et al, 2015). Treatment with Lasunairandadi Kashayam statistically improved chest heaviness, chest pain, and palpitations in the interventional group compared with the standard therapy group. Pedal edema, or swelling of the feet and ankles, can be associated with various medical conditions, including CAD (Khadka et al, 2019). The patients in the interventional group administered Lasunairandadi Kashayam displayed a noteworthy improvement in pedal edema. It can, therefore, be concluded that treatment with Lasunairandadi Kashayam significantly improved various parameters associated with CAD.

A. sativum, commonly known as garlic, is one of the major ingredients of Lasunairandadi Kashayam. It has been studied for its potential cardiovascular benefits, including its impact on CAD (Ginter & Simko, 2010; El-Saber Batiha et al, 2020). Several studies suggest that garlic may modestly reduce low-density lipoprotein cholesterol, commonly known as "bad" cholesterol (Sun et al, 2018; Aslani et

al, 2016; Kheirmandparizi et al, 2021). Elevated low-density lipoprotein cholesterol is a known risk factor for cardiovascular diseases. Additionally, garlic has been associated with a modest increase in high-density lipoprotein cholesterol, referred to as "good" cholesterol (Bayan et al, 2014). Higher levels of high-density lipoprotein cholesterol are generally considered beneficial for heart health (Franczyk et al, 2021). Some studies have suggested that garlic supplementation may have a triglyceride-lowering effect (Kheirmandparizi et al, 2021). Elevated triglyceride levels are another cardiovascular risk factor. In the present study, the level of low-density lipoprotein and triglycerides significantly decreased, whereas a slight increase in the high-density lipoprotein level was recorded, which may be due to the impact of *A. sativum* in Lasunairandadi Kashayam. In addition, *R. communis*, *Z. officinale*, *S. indicus*, and *C. bonduc*, other ingredients used for the preparation, have also been noted for their anti-hyperlipidemic activity (Jayan et al, 2017; Salih et al, 2023; Alizadeh-Navaei et al, 2008; Ramachandran, 2013; Iftikhar et al, 2020). Hence, it can be concluded that all the ingredients used in the preparation of Lasunairandadi Kashayam possess anti-hyperlipidemic activity, making it an effective cardioprotective formulation by lowering bad cholesterol.

Furthermore, our results demonstrated that the interventional group recorded a significant reduction in systolic and diastolic blood pressure. Some studies suggest that *A. sativum*, *Z. officinale*, *C. bonduc*, and *S. indicus* may have a hypotensive effect (Ried, 2019; Hasani et al, 20119; Galani et al, 2010). Accordingly, it can be concluded that the observed hypotensive effect in the interventional group may be due to the presence of this potent medicinal plant in Lasunairandadi Kashayam.

Platelets play a pivotal role in thromboembolic diseases, particularly in response to arterial vascular injury. Upon vascular injury, platelets swiftly adhere to the exposed subendothelial area and become activated by stimuli such as collagen, leading to the recruitment of additional platelets from circulation to form a stable arterial plug (Ren et al, 2010). It is widely acknowledged and confirmed that antiplatelet therapy remains crucial in the treatment and prevention of arterial thromboembolic disorders, such as CAD and stroke (Ren et al, 2010). Antiplatelet drugs constitute a significant class of pharmacological agents that disrupt the physiological activities of platelets and inhibit the formation of blood clots. Antiplatelet drugs are commonly prescribed for patients with a history of CAD, myocardial infarction, angina, atrial fibrillation, and other related conditions. The ingredients present in Lasunairandadi Kashayam such as garlic and ginger are reported to have antiplatelet effects.

CONCLUSIONS

In summary, the present clinical investigation into Lasunairandadi Kashayam as an add-on therapy for CAD patients has yielded valuable insights regarding its potential therapeutic benefits. The study's findings indicate promising outcomes in terms of the drug's efficacy for managing and potentially treating CAD. The study demonstrated a noteworthy reduction in key indicators of CAD, such as the TMT score, DOE, chest heaviness, chest pain, lipid profiles, and enhancement of overall cardiovascular health among the participants. These positive outcomes support the hypothesis that Lasunairandadi Kashayam may be crucial to addressing CAD. Moreover, the observed outcomes were consistent across diverse patient profiles, indicating the drug's potential

applicability across a broad range of individuals with CAD. The safety profile of Lasunairandadi Kashayam was also encouraging, with minimal reported adverse effects. While these results are promising, it is important to acknowledge the need for further research and larger-scale clinical trials to validate the findings and establish the long-term efficacy and safety of Lasunairandadi Kashayam. Additionally, comparative studies with existing conventional treatments could provide a more comprehensive understanding of its place in the therapeutic landscape for CAD.

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Availability of Data and Materials
The data sets utilized and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Consent for Publication
Not applicable.

Conflict of Interest
The authors declare that they have no competing interests.

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