

Original Research Article

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Effect of a reverse diet kit on the regression of atherosclerosis plaque and its effect on the lipid profile in patients with coronary artery disease

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ABSTRACT

Background: Prevalence of coronary artery disease (CAD) constitutes a major public health problem in developing countries. CAD also represents a major economic burden on health care systems and eventually creates a large gap in the quality of care associated with the disease.

Methods: To study ayurveda based disease and symptoms modifying therapy (Dietary modification and panchakarma therapy) to reduce symptoms of CHF and IHD and focus on reduction of total atheroma volume (TAV); plaque burden by a scientifically designed kit (Reverse diet kit) by Madhavbaug using a pre and post-test experimental design for patients with CAD.

Results: At the end of 90 days, a coronary CT angiogram revealed that TAV decreased significantly by 71.76 mm^3 in post-intervention plaque volume compared with baseline in the three major epicardial branches of the coronary artery.

Conclusions: The data provided relevant real-world evidence that the 'Reverse Diet Kit' can modulate coronary artery plaque deposition by reducing lipid infiltration within the coronary plaque and may lead to disease reversal wherein panchakarma therapy enabled symptom management and helped improve cardiovascular outcomes in patients with CAD.

Keywords: Reverse diet kit, CAD, Dietary modification, CT angiogram, TAV

INTRODUCTION

The global prevalence of mortality due to cardiovascular disease is steadily increasing and is projected to grow to around 23.4 million by 2030.¹ CAD may be asymptomatic or present with complications of diabetes mellitus, hypertension, obesity, and high cholesterol levels¹ leading to atherosclerosis. These alarming statistics and clinical manifestations associated with the disease highlight the urgent need for timely diagnosis, risk stratification, and management of symptoms in patients with CAD. This has further led to a plethora of newly available conventional CAD management strategies which involve medications and surgical interventions, that have revolutionized the current treatment strategies in patients with CAD. However, in

developing countries like India, their adoption in clinical practice has been slow due to the associated financial burden, in terms of direct (e.g., surgical procedures, hospitalizations, rehabilitation services, physician visits, drugs) and indirect costs associated with the treatment strategies.

The current study thus focuses on a holistic approach to the management of symptoms associated with CAD by panchakarma therapy which is a combination of modern diagnostic research based on Ayurveda and scientific lifestyle modification and further targets reduction in plaque formation using a reverse diet kit, a scientifically designed kit by Madhavbaug. Madhavbaug's programs allow specialists to use cutting-edge technology to recommend specialized diets and lifestyle modifications to patients to offset the risk of heart disease. The current

study assessed the impact of reverse diet kit, and panchakarma therapy using a pre and post-test experimental design for patients with CAD. The diet box contained pre-portion ready-to-cook food products that fulfill the daily requirements of breakfast, lunch, dinner, soup, and early morning diet. The reverse kit diet food consisted of a high oxidative radical absorption capacity (ORAC) unit i.e. 64,000 per day. The normal requirement of a normal subject is 12000 ORAC units per day whereas conventional food can serve 3000-4000 ORAC value. The reverse diet kit is custom-made to help the antioxidant system of the patient to be active. The added advantage, that the kit has over other prescribed diets to date, is enabling the patient to achieve the target energy deficit.

Daily intake of 1000Kcal diet was made such that the patient would be calorie deficit and, ultimately to meet the normal requirement of 1500 Kcal/ day, body fats would be utilized leading to a reduction in visceral obesity. Madhavbaug's non-invasive heart treatment also included different types of therapies such as an ischemia reversal program (IRP), heart failure reversal therapy (HFRT), and plaque stabilization treatments to prevent vascular inflammation.

The IRP is a combination of Panchakarma and allied therapies kit which uses a combination of Snehana (Centripetal oleation), Swedana (Thermal vasodilation), and Basti (Per rectal drug administration) for providing relief to the symptoms associated with CAD.² This program is designed to improve the blood flow to the heart, thus reducing the risk of heart attack and increasing exercise tolerance levels to improve the quality of life.

Furthermore, several studies have also reported novel device-based therapies and innovative strategies such as lipid-lowering by statins which can stabilize or even regress plaque by reducing lipid accumulation, and inflammation, or by improving endothelial functioning.^{3,4} Even though these medications have led to a marginal reduction in cardiac morbidity and mortality, there are still considerable residual risks that need to be understood and managed, with a proper balance of lifestyle changes. However, there is a paucity of data that formally evaluates the use of Ayurvedic-based treatment in the risk stratification of disease progression in such patients.

Hence the current study is intended to examine the feasibility and effectiveness of a comprehensive ayurvedic lifestyle-based modification program which includes incorporating a balanced diet (reverse diet kit), meditation, breathing exercises, yoga, and antioxidant-rich foods in patients with varying severity of coronary heart disease.

The main aim of the study is thus to evaluate the effect of a reverse diet kit on the regression of atherosclerosis plaque and to further study its effect on the lipid profile in patients with CAD.

METHODS

Study design

We performed a prospective, real-world evidence-based study conducted from March 2020 to February 2021 on 149 patients with CAD, with clinical evidence of atherosclerosis plaque who had visited the Madhavbaug clinics, India.

Selection criteria: Adult patients (30-80 years, male or female) diagnosed with CAD were included in the study. Patients with a history of coronary artery bypass grafting (CABG) and percutaneous transluminal coronary angioplasty, or patients having severe symptoms and who may require emergency surgical intervention were excluded from the study.

The patient information sheet was explained to each patient, in the language understood by them in the presence of the doctor and patients' relatives. On agreeing to participate in the study, signatures on the patient information sheet and informed consent were obtained from all patients. The procedures followed were based on the ethical standards of the responsible committee on human experimentation (institutional or regional) and the Helsinki declaration of 1975, revised in 2000.

The dietary modification was considered to be the cornerstone for the treatment and reversal of plaque burden in patients with CAD, and hence reverse diet kit was prescribed to all 149 patients enrolled in the study. Panchakarma therapy is aimed at improving long-term CAD-associated complications by alleviating symptoms to increase longevity.

Hence the study population was further divided into three groups based on the symptoms and intensity of pain concerning varying severity of the disease presented by the patient at the time of admission and appropriate Panchakarma treatments were provided to them. Group 1: patients with chronic heart failure who underwent HFRT, group 2: patients with ischemic heart diseases who underwent IRP treatment, and group 3: patients who did not show any symptoms were subjected to plaque stabilization treatments.

Owing to the clinical conditions and hospitalization trauma associated with the disease, the patients were also seen to be suffering from anxiety and depression. Therefore, in the first session, behavioral therapy and counseling sessions were conducted to revive the patient's hope and give them a full description of the treatment process. A well-designed diet plan was then prescribed to carefully control the energy and macronutrient requirements of the patient.

The patients' relatives were advised to treat them with kindness and were asked to maintain a disciplined follow-

up routine. In the next step, measures were taken such that the patients would be encouraged to walk in nature at least several times a week to relax and get some fresh air. The patients were also provided with a nutrition guide to apply all dietary and drinking instructions, and in particular, they were advised to avoid overeating and were asked to consume more vegetables and fruits as per the diet plan provided. There were also recommendations for regulating their sleep patterns, to have a relaxed and stress-free environment. In addition to a low carbohydrate diet plan, based on the severity of their disease and pain, appropriate Panchakarma therapies were provided to improve VO₂ peak and Duke treadmill score (DTS) in patients with CHF and IHD respectively. Moreover, anti-inflammatory plaque stabilization panchakarma is aimed at preventing further vascular inflammation to further improve the quality of life. Asymptomatic patients underwent anti-inflammatory plaque stabilization panchakarma to prevent further vascular inflammation.

All the recruited subjects underwent routine 128 slices multi-detector coronary CT angiography (CCTA) with plaque volumetric analysis for CAD diagnosis and to reflect the extent of plaque deposition at the time of recruitment. The 128-slice multi-detector coronary CCTA has emerged as a cost-effective and accurate non-invasive imaging modality to diagnose CAD.^{5,6} CCTA allows the evaluation of coronary plaque burden and its compositions. Characteristic of plaque was differentiated into lipid core, fibrotic, and calcified based on the radiopacity of plaque tissues calculated with the help of the Hounsfield unit, volume of total plaque, and various characteristics calculated by using Siemens software.⁷ This has enabled the prediction of adverse cardiac events and prognosis, without an observation period with cardiac biomarkers or serial ECGs. IVUS is an invasive procedure that is not commonly performed in routine clinical practice and thus may be limited to research studies.⁸ However, several studies that compared CCTA with intravascular ultrasound have validated the role of CCTA in the detection of coronary plaques, with the same accuracy of plaque volume prediction as IVUS.^{9,10} Furthermore; we also analyzed maximum aerobic capacity (VO₂ peak) in patients with non-IHD CHF and DTS in patients with IHD, to assess the impact of the therapies on the quality of life. Lipid profile analysis, blood pressure, BMI, ABG, a part of routine check-up and follow-up, assessment of weight, BMI, and ABG were repeated on the 30th day of every month for 90 days. To evaluate the effectiveness of the therapy on lipid profile, the amount of reduction in allopathic medications consumed by the patients was also analyzed from baseline to post-intervention of 90-day therapy.

Statistical analysis

Statistical analysis was done using SPSS statistical software (version 27). Descriptive statistics (number and percentage) were used to express baseline characteristics like gender distribution and proportion of patients having

plaque volume change at the end of follow-up (90 days after therapy). Mean values were expressed for well distributed data points. The parameters assessed at follow-up were compared to baseline by paired t-test. Univariate as well as multivariate regression analyses were used to evaluate baseline determinants for change TAV and plaque volume. A p value of less than 0.05 was considered statistically significant. No specific sample size calculation was carried out at the beginning of the study.

Reverse diet kit

The patient was started on an intervention in which he was advised to incorporate a scientifically created reverse diet kit into his daily routine in addition to the prescription medications and an antioxidant-rich, anti-inflammatory, low-calorie diet.¹¹ The patient adhered to a weekly meal plan created according to his caloric needs throughout the 90 days of the research.

RESULTS

The screening and the enrolment process for the treatment protocol conducted in the study are summarised in the flow chart above (Figure 1). Thus, in the current study, data of 149 patients with CAD at the time of recruitment and the end of the 90 days is presented and evaluated, wherein, out of 678 individuals screened, only 180 who fulfilled the inclusion criteria were enrolled for the study. However, by the end of the therapy tenure, 31 out of 180 patients discontinued and hence dropped out and the total number of study subjects recruited scaled down to 149. The recruited subjects were then followed up, for 90 days.

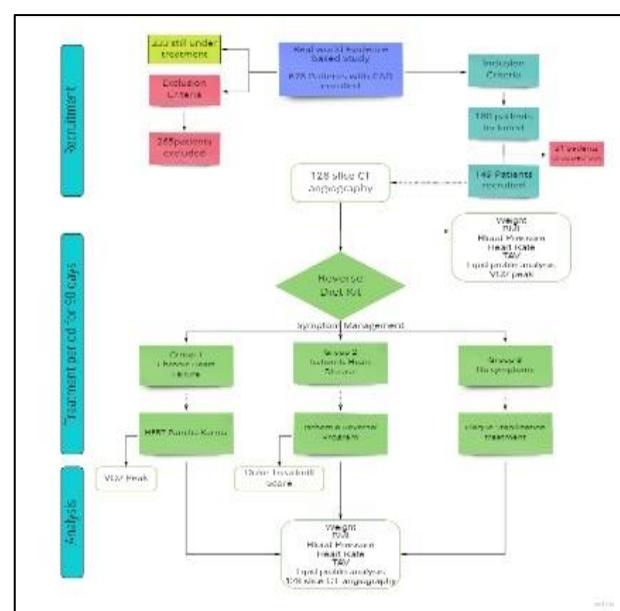


Figure 1: Summarising screening, treatment, and analysis protocol followed in the current study.

Table 1 shows the demographic data depicting the weight, BMI, blood pressure, and heart rate of the patients at baseline i.e., at the time of the recruitment and after a follow-up period of 90-day therapy. The mean values observed showed that there was a significant reduction in the anthropometric data at the end of the follow-up period.

The present study aims to determine the pre and post-plaque volume of the three major epicardial branches of the coronary artery. 128-slice multi-detector CT angiography was performed which showed a significant reduction in the plaque volume.

As depicted in Figure 2 total atheroma plaque volume (TAV) decreased significantly by 71.76 mm³ in post-intervention plaque volume compared with baseline in the four major arteries. Furthermore, after the follow-up period, changes in calcified, fibrotic, fibrofatty, and lumen plaque were found to reduce significantly from 108.33 mm³, 376.85 mm³, 55.38 mm³ and 1073.88 mm³ to 96.36 mm³, 327.20 mm³, 44.56 mm³ and 1120.58 mm³ respectively. Moreover, Table 2 depicts the reduction of TAV in patients from different groups concerning the different treatments provided to them based on their disease presentation. Regardless of the number of kits, a reduction of over 67% was seen.

Laboratory assessment values of total cholesterol, triglycerides, LDL, HDL, and HbA1c were done. Furthermore, Figure 3 shows that even though mean values of total cholesterol, LDL, and HDL levels were found to decrease they were not statistically significant whereas triglycerides and HbA1c levels reduced significantly at the end of the 90-day follow-up. Interestingly, clinically significant changes were noted in the TAV-improved group, wherein the median values of LDL were found to reduce from baseline to the end of 90-day therapy. No improvement concerning LDL levels was recorded in the non-improved TAV group. After 12 weeks of intervention change in plaque in fibrotic and fibrofatty plaque was observed. Soft plaque is reduced. However calcified plaque didn't show a significant reduction. Significant improvement in VO₂ peak and DTS score concerning TAV reduction value was observed. Reduction in TAV is not correlated to age. In the trial, it was observed that statin therapy lowered LDL median values from 124 to 87.5 and raised HDL levels from 42.5 to 45.1, which was further found to be

associated with a significant reduction in all IVUS measures of atheroma burden. The Figure 2 represents plaque reduction in all vessels and percentage change in the vessels respectively. Figure 3 illustrates the trend observed in the lipid profile of the patients before and after therapy. Furthermore, in our current study, as depicted in Table 3, after the 90-day therapy, a significant reduction in the number of medicines consumed by the patients was also observed.

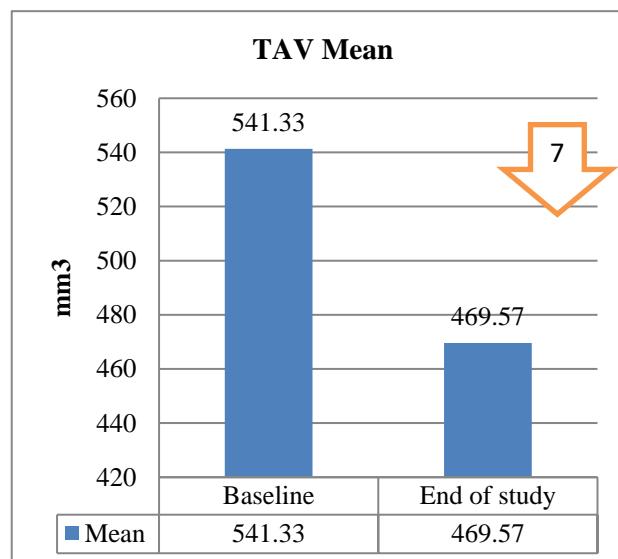


Figure 2: Total atheroma plaque volume.

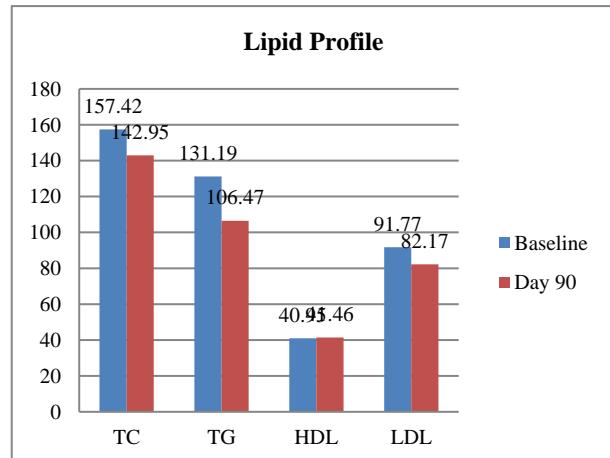


Figure 3: Lipid profile of the patients with CAD.

Table 1: The demographic data depicting weight, BMI, blood pressure, and heart rate of the patients.

Variables	Before	After	Difference	P value
Weight	71.16±10.83	64.56±10.23	6.61±3.44	<0.0001**
BMI	26.54±3.61	23.97±3.26	2.56±1.70	<0.0001**
HR	78.54±12.52	74.78±10.56	3.39±12.68	0.0024**
SBP	127.66±17.08	91.12±18.62	9.12±18.62	<0.0001**
DBP	78.27±9.97	75.56±9.94	2.65±12.44	0.0155**
HbA1c	7.69±2.27	6.41±1.59	1.67±1.97	<0.0001**

*BMI-Body mass index, DBP-Diastolic blood pressure, HR-Heart rate, SBP-Systolic blood pressure. ** statistically significant

Table 2: Relation with total no of diet kit and reduction of TAV in (%).

Total no of diet kit	No reduction in TAV, n (%)	Reduction in TAV, n (%)	Total
1	3 (33.33)	6 (66.67)	9 (100)
2	34 (32.07)	72 (67.93)	106 (100)
3	11 (32.35)	23 (67.65)	34 (100)

Table 3: Medicines consumed by patients before and after therapy.

Medicines	Baseline	Day 90	Percent reduction
Statin	105	45	51.14
ARB	38	29	23.68
CCB	22	5	77.27
Beta-blocker	66	26	60.61
Nitrate	40	12	70

ARB-Angiotensin receptor blockers, CCB-Calcium channel blockers.

DISCUSSION

The coronary atheroma volume depicting the burden and progression of coronary atherosclerosis is known to be associated with adverse cardiovascular outcomes.^{4,12} This has further led to considerable interest in characterizing the effect of medical therapies on plaque composition, associated with acute coronary syndromes containing lipid, inflammatory, and necrotic particles.

In the present observational study, we observed that the implementation of an appropriate care plan involving a reverse diet kit and panchakarma therapies has led to significant regression in TAV along with plaque burden in fibrous tissue. Our findings also reflect that lowering LDL cholesterol levels can be achieved by appropriate lifestyle and diet modification and can further lead to a reduction in coronary diseases even in the absence of allopathic medications. Taken together, these data provide preliminary evidence that the reverse diet kit along with appropriate panchakarma treatment in patients with CAD can modulate coronary artery plaque deposition by reducing lipid infiltration within the coronary plaque. Furthermore, it has also shown remarkable success in the early clearance of the already deposited plaque leading to CAD block reversal by preventing further progression into an advanced cardiovascular condition like unstable angina, acute myocardial infarction, and sudden death.¹

Atherogenesis is a complex process, in which deposits of lipids appear in the intima of large muscular and elastic arteries, which further progresses through several stages ultimately leading to clinical manifestations of CAD.^{13,14} Thus, abnormal lipid metabolism remains the crux of the pathogenesis of CAD, on which inflammatory and other mechanisms superimpose. Hence several approaches such as the use of statins, -blockers, angiotensin-converting enzyme (ACE) inhibitors, antithrombotic drugs, and proper use of estrogen and antioxidants have been proposed to counter the progress of the development of atherosclerosis.^{15,16} However, there still seems no consensus as to the best pharmacological option to

control the progression or to reduce the occurrence of risk factors of this disease.

Hence in the present study, carbohydrate recommendations via the reverse diet kit mainly focus on low glycaemic index sources to help in weight loss programs. It also aims at reducing inflammation, triglycerides, and high-density lipoproteins to further aid the improvement of vessel health. In our study, reductions in the median values of LDL levels observed in the TAV-improved group were in corroboration with the results of the ASTEROID trial, a study conducted to investigate the impact of rosuvastatin on intravascular ultrasound-derived coronary atheroma burden (ASTEROID) at 53 community and tertiary care centers in the United States, Canada, Europe, and Australia.¹⁷

Low glycaemic index foods potentially play a crucial role in weight regulation, reduction in inflammation, triglycerides, and high-density lipoproteins with improvement in vessel health.¹⁸

The kit had an added advantage wherein, in 90 days, the kit enables the reduction of body weight by around 10%. Daily intake of a 1000 Kcal diet made the patient calorie deficit. Ultimately to meet the normal requirement of 1500 Kcal/ day, body fats were utilized which further led to weight loss and eventually reduced atherosclerotic plaque progression.

On the other hand, oxidative stress is another factor, known to initiate a cascade of vascular events like endothelial dysfunction, inflammation, and thrombus formation which can lead to atheroma progression.^{19,20} The reverse diet kit had a high ORAC unit which enabled the antioxidant system of the body to switch on 24 by 7. The reverse diet kit was planned such that along with low glycaemic foods, the patient was also provided with foods rich in vitamin A, vitamin C, and vitamin E to increase the patient's antioxidant capacity to kill toxic products generated; like pro-inflammatory products and free radicals. Several large-scale clinical studies have observed that an increased antioxidant level is an

important factor in limiting the risk of cardiovascular events associated with CAD.²¹ High dietary intakes of vitamin C, vitamin E, and beta-carotene are associated with a lower risk of CAD and showcase improved life expectancy which is supported by increasing evidence from trials using antioxidant supplements.²² In a randomized, controlled clinical trial performed on a total of 2002 patients with angiographically-proven CAD, it was observed that with an overall risk reduction of 47% the combined end-point of non-fatal myocardial infarction and cardiovascular death, was prevented with vitamin E supplementation.²⁰

Furthermore, foods like pomegranate, garlic, and fiber-rich low carbohydrate food enhanced the defence mechanism against inflammation leading to the reversal of disease progression.²³ Our study was in corroboration with the above reports which showed significant improvement in the TAV of the patient post-90-day therapy. It also enabled increased blood flow and paved the way toward a reduction in plaque formation. The diet kit being anti-inflammatory and having high anti-oxidant capacity might have helped in the reversal of disease progression, thereby improving vessel health, leading to reduced plaque volume and improved blood flow. Reverse diet kit thus led to atherosoma regression to a significant level and also enabled tapering of allopath medications through diet management and lifestyle changes by panchakarma therapies. Snehana is an important ayurvedic procedure that has been shown to anti-anxiety effect which eventually is known to reduce the sympathetic overactivity associated with IHD.²² Sweden and Basti play an important role in the management of obesity by improving sodium and fluid retention thus reducing the myocardial oxygen demand in patients with IHD.^{24,25} In the current study three types of Basti were undertaken; HFRT to reduce dyspnoea, IRP for exertional angina, and PLS for anti-inflammatory effects.

Although the study outcomes have been beneficial for the patients, the study sample size is a limitation and there was no control group for head to head comparison therefore the study results cannot be generalized and a long term, randomized double-armed study is warranted.

CONCLUSION

The current study focused on identifying high-risk plaques and provided a substantive basis for the development of a treatment regime comprising a scientifically designed reverse diet kit along with panchakarma. Notably, the reverse diet kit led to the reversal of the diseased condition to a significant level whereas panchakarma might have enabled symptom alleviation, improving the quality of life to a great extent. Our clinical study has thus provided evidence-based outcomes and promoted a therapeutic approach to bring out the phenotypic changes in plaques that are associated with stabilization in the diseased condition.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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