

Effect of Yoga Based Lifestyle Intervention on Coronary Artery Disease Patients

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This study was designed to evaluate the impact of yoga based lifestyle intervention on coronary artery disease (CAD) patients. This multi-centric prospective study was held in the Saaol heart center in different cities (Delhi, Kolkata, Bangalore, Chennai, and Mumbai) of India from 1995 to 2015. In this study, total 5,000 CAD patients having co-morbidity of obesity, hypertension, and diabetes were enrolled. A yoga-based lifestyle modification counseling (consist the essential components; cardiac education, plant-based balanced diet, regular walk, yoga, and meditation) was administrated to study subjects and clinical assessment was done using Saaol safety wheel as a holistic tool. In the beginning, lifestyle modification counseling was provided every month for one year and after one year the counseling was repeated for every six months with clinical assessment till the end of the study 5 years follow up. The results of this study demonstrate a significant improvement in angina with reduction of New York Heart Association (NYHA) angina classification score from 3.08 ± 0.56 (mean \pm SD) to 2.45 ± 0.70 and also reduced the intake of anti-anginal drugs from 4.36 ± 1.35 to 3.82 ± 1.20 . In this study, a significant improvement was also observed in heart attack protection score from 56.68 ± 13.53 to 104.13 ± 14.55 . After the adherence to yoga-based lifestyle modification counseling components and Saaol safety wheel, 98% study subjects showed the significant improvements in clinical outcomes (BMI, blood pressure, and lipid parameters) and cardiac patients reduced the risk of heart attack and cardiac events. This study concludes that yoga-based lifestyle intervention is a non-invasive effective treatment method to control and prevent cardiac risk factors in CAD patients. This type of holistic approach may help to reduce the rate of cardiac events and heart attacks but there is further long-term multicentric randomized controlled trials are required for better clinical outcomes.

Keywords: Coronary Artery Disease, Risk factors, Heart disease, Cardiovascular events.

Cardiovascular diseases (CV) are the prime cause of premature death and disabilities throughout the world, more people die annually from CVDs when compared with any another cause. About 17.5 million people died from CVDs annually, representing 31% of all global deaths. Cardiovascular disease, especially coronary Artery Disease (CAD) is the leading cause of morbidity

and mortality globally with more than 17.3 million deaths annually. CAD is responsible for about 15% of all deaths in the world. It is the number one killer in India and has a prevalence of 11% in urban and 5% rural settings. The problem of chronic diseases, including CAD, is rapidly rising worldwide. It is estimated that, by 2020, these diseases will be the cause of almost several quarters of all deaths



worldwide understanding that 71% of deaths caused by coronary heart diseases (CHD), 75% of deaths caused by the stroke in addition to 70% of deaths caused by diabetes can occur throughout developing countries. Using a global foundation, 60% of the burden of chronic diseases will come about in developed countries. Cardiovascular diseases are however more quite a few in India and China than in all the developed countries on the globe put together.¹⁻¹²

CAD is associated with a higher risk of cardiovascular events, including myocardial infarction (MI) and stroke. The prime cause of CAD is modern lifestyle and urbanization and several risk factors such as dyslipidemia, hypoglycemia, high triglyceride, hypertension. Obesity increases the progression of endothelial injury and develops atherosclerosis, which further causes serious cardiac arrest; heart attack.^{6,13}

Numerous clinical research studies, including the Framingham, indicated the major risk factor for CAD includes high cholesterol, high triglyceride, low HDL, hypoglycemia, smoking, fatty food, excess intake of oil, lack of exercise, walking and less fibrous diet, stress. Changing of the modern lifestyle with medication can prevent coronary artery disease and the complication of preventive therapy for coronary artery disease patients. Primary prevention of CAD consists of interventions promoting a healthy lifestyle in the general population.⁸

CAD risk factors can be modified by lifestyle changes and it has been observed by various research studies that lifestyle changes can reduce the morbidity and mortality of CAD. Lifestyle modification counseling is the primary goals for prevention and control of CVD, and may significantly improve cardiac risk factors. Lifestyle modification counseling (LMC) commonly used as an intervention tool, is a novel, non-invasive method to control CHD, T2DM, hypertension and other lifestyle-related chronic diseases. LMC includes- education about the disease (CHD), self-management and behavior change counseling, balanced diet, weight management, physical activity (walk, and yoga), tobacco and smoking cessation, and stress management counseling. Several studies showed that a poor knowledge about disease is associated with a higher BMI,

prolonged use of medicines, poor glycemic control, and more complications and co-morbidities. Hence, patients require repeated health education and lifestyle modifying interventions through physicians and other health educators.¹⁴⁻¹⁶

A study done by Artinian *et al* demonstrates the effectiveness of lifestyle modification counseling with significant improvement in cardiovascular health and significant reductions in BMI, systolic and diastolic blood pressure, total cholesterol, fasting glucose and as well as improvements in physical activity and medication adherence. Lack of awareness and non-adherence to lifestyle modification program due to complexity in content and counseling are the aspects that encourage conduct SAAOL Heart Study for preventing of coronary artery disease. To investigate this approach, a comprehensive, holistic model is used to prevent and manage coronary heart disease risk factors that reduce serious cardiac events such as heart attack and stroke.¹⁷⁻¹⁸

There are only a few studies in India, which have attempted to establish a comprehensive lifestyle modification counseling approach with larger populations and assessing long-term effectiveness of LMC. We aimed to introduce such intervention and hypothesized that lifestyle modification counseling will be more effective and will improve cardiac health in CHD patients. Therefore, the aims of this study were to evaluate the impact of the SAAOL lifestyle program using a holistic model in the prevention of coronary artery disease.

MATERIALS AND METHODS

Study design and setting

This was a multi-centric prospective lifestyle intervention study, which was conducted in the SAAOL Heart Center in different cities (Delhi, Kolkata, Bangalore, Chennai & Mumbai) of India from September 1995 to December 2015. In this study, total 5,000 CAD patients with and without co-morbidity (Obesity, Hypertension, and Diabetes Mellitus) was enrolled based on a consecutive sampling technique. This study was conducted in two phases. In the first phase of planning, preparation for counseling components and recruitment of participants was done and in the

second phase the implementation of counseling, data collection, follow-ups, and data analyses. The consort diagram is given in Table 1.

Eligibility criteria

The patients were included in this study if they were clinically and diagnostically confirmed coronary artery disease with and without comorbidity (obesity, hypertension and diabetes mellitus) patient either sex, aged 30 years to 70 years, CAD patients having symptoms of angina, Patients with coronary artery disease and unsuitable response to medical treatment and not willing for CABG (Coronary Artery Bypass Grafting) & PTCA (Percutaneous Trans Coronary Angioplasty), patients with angiographically documented and having at least one vessels disease (blockage in any 3 main arteries RCA, LAD, LCX more than 70%) and willing to participate and able to give valid written informed consent. The patients were excluded if they were having several conditions such as peripheral arterial disease, cerebrovascular disease, Renal artery stenosis, aortic aneurysm, pulmonary heart disease, cardiac dysrhythmias, inflammatory heart disease, endocarditis, inflammatory cardiomegaly, myocarditis, valvular heart disease, congenital heart disease, rheumatic heart disease and pregnant woman and unwilling to participate and give written consent.

Sample size

A total of 5,000 subjects was recruited based on consecutive sampling technique from the SAAOL Heart Centre, Delhi. The minimum calculated sample size for this study was 4147 with a margin of error 2% and confidence of the interval of 99%.

The sample size for the proposed study was calculated by the standard formula

$$N = Z^2 p (1 - p) / e^2$$

Here, Z is the corresponding confidence interval, e is the margin of error and p is the estimated value of the proportion of samples having the condition of interest.

Lifestyle intervention

The intervention of the study participants commenced in 1995 and ended in 2015. The minimum 5-year intervention program consisted of two phases; with an active period (continuous Lifestyle modification counseling for one year at every month) and the maintenance period

(Lifestyle counseling was provided at six-month intervals for four years). Lifestyle modification counseling through the Saaol safety wheel was used as an intervention tool for participants to prevent and control CHD. The Saaol safety wheel was developed as a tool for heart patients to follow their progress and also to find out their fault. The Saaol safety wheel has three wheels- one for reversing heart disease (green wheel), one for keeping blocks at a steady level (yellow wheel) and one for growing the blockage (red wheel). The Saaol safety wheel has 18 components (cholesterol, triglyceride, HDL ratio, systolic and diastolic blood pressure, blood sugar fasting, blood sugar PP, tobacco/smoking, BMI, walk, oil intake, milk intake, fruit intake, salad intake, animal food intake, yoga, meditation, and stress level) marked at the level of green, yellow and red, as per their levels in the body. Saaol safety wheel is described in the below figure.

Measurement and follow up of the study participants was done at baseline, 1st, 3rd and 5th year. The research team were prepared to study materials, support and supervised the lifestyle intervention sessions. All lifestyle intervention sessions were coordinated and facilitated by the trained and qualified dietitian, yoga teacher, and heart care expertise under the supervision of research expert in the SAAOL heart center, New Delhi. The intervention components were described through counseling in the local language, supported by pictures, videos, and discussions with separable or a group of patients. Each session took approximately 15-20 min and the five counseling components described in table 2.

Measurements

Demographic details (Age, sex, medical history, family history) of the study participants had been done at baseline. The outcome measures for this study was BMI, systolic and diastolic blood pressure, pulse, total cholesterol, triglyceride, LDL cholesterol, HDL cholesterol, blood sugar fasting, blood sugar PP, and adherence to counseling or SAAOL safety wheel. The measurement of all study outcomes was assessed at baseline, 1st, 3rd and 5th year follow up. Height and weight of the participants were measured using a 'Stadiometer' and 'SECA' digital scale, and BMI was calculated using the formula of weight in kg divided by height in m² (kg/m²). Trained personnel assessed the blood

pressure using 'Pagoda (mercury) B.P' instrument. Cholesterol was assessed by the CHOD-PAP method, triglyceride by GPO method, HDL-cholesterol by immune inhibition method and LDL was calculated using a standard formula [LDL = Total Cholesterol - HDL - (Triglycerides/5)]. Fasting and PP blood glucose tests were analyzed using 'Contour Plus One' blood glucose monitoring system. Adherence to lifestyle intervention (saaol safety wheel) among CHD patients were assessed through SAAOL heart attack protection score. This is a unique scoring system to assess the adherence of the saaol safety wheel. The total possible score was 180 if the score above 90 or 50 % score indicated good adherence.

SAAOL Heart Protection Scoring was as follows ; Cholesterol (below 130mg/dl=10, 130-149mg/dl=5, 150-180mg/dl=1, above 180mg/dl=0), Triglyceride (below 100mg/dl=10, 100-129mg/dl=5, 130-160mg/dl=1, above 160mg/dl=0), HDL/Cholesterol percentage (above 40%=10, 25-40%=5, 20-24%=1, below 20%=0), Systolic B.P (below 120mmHg=10, 120-129mmHg =5, 130-140 mmHg =1, above 140 mmHg =0), Diastolic B.P (below 80mmHg=10, 80-89mmHg =5, 90-100 mmHg =1, above 100 mmHg =0), Fasting Blood Sugar (below 100mg/dl=10, 100-109mg/dl=5, 110-120mg/dl=1, above 120mg/dl=0), PP Blood Sugar (below 140mg/dl=10, 140-159mg/dl=5, 160-200mg/dl=1, above 200mg/dl=0), Tobacco (Zero=10, One/day=5, 2-3/day=1, more than 3/day=0), BMI (below 24 kg/m²=10, 24-24.9 kg/m²=5, 25-26 kg/m²=1, above 26 kg/m²=0), Walking per week (5-7d/week=10, 3-4d/week =5, 1-2d/week =1, Nil=0), Oil intake (Zero Oil=10, Negligible=5, Limited=1, Unlimited=0), Milk intake (below 200 ml (Skimmed)=10, 200-250ml (double toned)=5, 250-300 ml (Full cream) =1, above 300 ml (Full cream)=0) , Fruits intake (5-7d/week=10, 3-4d/week =5, 1-2d/week =1, Nil=0), Salad intake (5-7d/week=10, 3-4d/week =5, 1-2d/week =1, Nil=0), Non-Veg (Animal) Food (None=10, one day/month =5, one day/week =1, almost everyday=0), Yoga (5-7d/week=10, 3-4d/week =5, 1-2d/week =1, Nil=0), Meditation (5-7d/week=10, 3-4d/week =5, 1-2d/week =1, Nil=0), Stress level (Negligible=10, Mild=5, Moderate=1, Severe=0), Total Score=180, Passing Mark = 90 (50%).

Statistical analysis

Statistical package for the social sciences (SPSS) software version 21 was used for all statistical analyses. In this study percentage, mean, SD, median and sample paired t-test, repeated measures and multi-variant analysis was done to assess the study parameters.

Ethical approval and consent

Ethical approval for this study was granted by the ethics committee of SAAOL Heart Center New Delhi. Informed consent has been obtained from all enrolled study participants.

RESULTS

Recruitment and response rate of participants

This was a prospective lifestyle intervention, which was held in SAAOL Heart Center, New Delhi from September 1995 to December 2015. A total 5,000 subjects were enrolled. After 5 years of follow up only 4510 subjects to complete the entire process of study and their data were analyzed.

Baseline characteristics of the participants

The mean age of study participants was 54.96±9.87. This study data has 3836 (85.06%) males and 674 (14.94%) females. The majority of patients have co-morbidity of obesity 1291 (28.63%), hypertension 1759 (39.01%), and diabetes 679 (15.06%). In this study, 1264 (28.03%) patients were having the family history of heart disease. The positive cases of TMT were 4069 (90.22%) in this study. In this study, the maximum number of double vessel disease (DVD), 4068 (90.19%) was documented, followed by TVD (5.14%) and SVD (4.67%). Participant having CABG history were 1209 (26.81%) and PTCA were 1485 (32.93%). Participants having MI history were 329 (7.29) in this study. EF of participants was 48.20±8.41 and HR mean of participants was 70.71±4.59. The baseline characteristics of the study subjects are presented in table 3.

Effect of LMC in Cardiac Risk Factors

A significant change was observed in cholesterol from baseline (175.43±44.82) to 5 years (128.97±47.72) of follow up with p<0.0001. There was also a significant change, observed in triglyceride from baseline (157.55±35.91) to 5th

year (99.77±19.52) of follow up. A significant increment in HDL/Cholesterol percentage was also observed from baseline (24.96±7.94) to 5th year (42.10±16.54) of follow up.

A significant reduction in systolic blood pressure was observed from baseline (135.02±19.89) to 5th year (117.06±5.32) of follow up with p<0.001. A significant reduction in diastolic blood pressure was also observed from baseline (87.54±9.69) to 5th year (75.28±5.01) of

follow up with p<0.001. There was a significant improvement in blood sugar fasting (106.47±29.44 to 98.47±23.81), blood sugar PP (140.88±66.50 to 128.97±47.72) was observed from baseline to 5th year of follow up. A significant improvement in BMI was also observed from baseline (25.71±3.90) to (23.98±4.34) with p<0.0001. The details of the results are given in table 4.

A significant improvement in other cardiac risk factors Tobacco consumption,

Table 1.

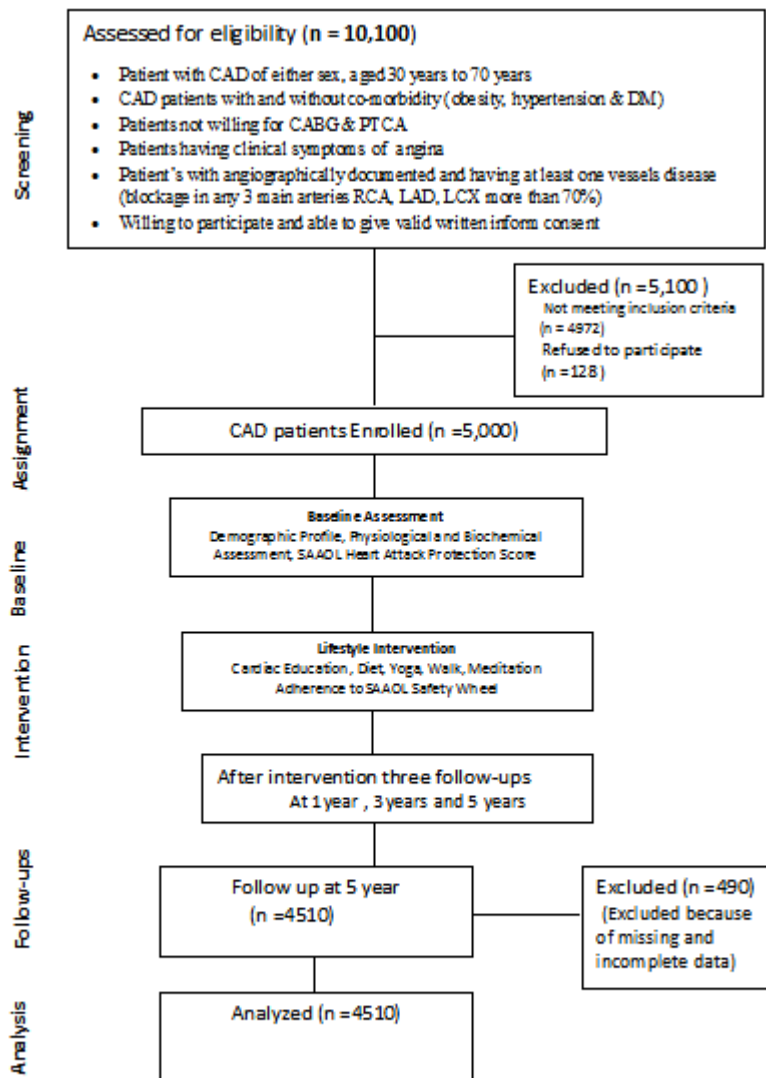


Table 2. Five key components of Lifestyle Modification Counseling (LMC) using the SAAOL Safety Wheel

Intervention	Sessions Conducted by	Description of the Intervention	Rationale
1. Cardiac Education	Heart care expert	Participants were educated about heart, heart diseases, heart attack, angina, signs and symptoms of angina, risk factors responsible for heart disease, complications and management of chronic diseases and emphasize the benefits of lifestyle modification; diet, walk, yoga, and meditation.	Cardiac education may increase awareness and adherence to follow a healthy lifestyle and help to reduce angina episode and preventing of coronary artery disease.
2. Balanced (Oil-free) diet	Dietician	Participants were encouraged to cut down high-calorie food, animal food and minimal milk intake (skimmed) and advised to increase the amount of fibrous food (whole grain, salad, green vegetables, and fruits). Participants with family were trained to prepare oil-free food. Study participants advised to follow and adhere to zero oil food with balanced diet chart and SAAOL safety wheel.	Balanced diet help in weight & blood pressure management glycemic control. Fibrous diet fruits reduce the blood sugar and cholesterol level.
3. Walking	Physical trainer	Participants were motivated to adhere on a regular brisk walk for at least 30 minutes per day.	Walking reduces the angina stability, blood glucose level, cholesterol and triglycerides, blood pressure, and improves the response to the anti-angina drugs.
4. Yoga	Yoga teacher	Training of yoga asana (Mudrasana, Balasana, Vajrasana, Paschimottasana, Ardha Matsyendrasana, Supta Vajrasana, Dhanurasana, Shavasana) was given and advised to adhere the practice for 30 minutes per day.	Yoga may reduce cardiac risk factors and improve angina stability, blood glucose level, cholesterol and triglycerides, blood pressure and also helps in stress management and improvement in health-related quality of life.
5. Meditation	Yoga and spiritual teacher	The participants were encouraged to do daily Preksha meditation and breathing exercise at least for 15 minutes to control stress.	During meditation, the level of stress hormone (adrenaline and cortisol) reduced which further help to reduce stress levels and improve cardiac health and glycemic control.



Table 3. Baseline demographic characteristics of participants

Baseline Characteristics of Study Participants		
Variables		n=4510
Age (Mean ± SD)		54.96±9.87
Gender (%)	Male	3836 (85.06)
	Female	674 (14.94)
Obesity (%)	Yes	1291 (28.63)
	No	3219 (71.37)
Hypertension (%)	Yes	1759 (39.01)
	No	2751 (60.99)
Diabetes (%)	Yes	679 (15.06)
	No	3831 (84.94)
Family history of Heart Disease (%)	Yes	1264 (28.03)
	No	3246 (71.97)
TMT (%)	Positive	4069 (90.22)
	Negative	441 (9.78)
Classification of CHD (%)	SVD	210 (4.67)
	DVD	4068 (90.19)
	TVD	232 (5.14)
CABG (%)	Yes	1209 (26.81)
	No	3301 (73.19)
PTCA (%)	Yes	1485 (32.93)
	No	3025 (67.07)
MI (%)	Yes	329 (7.29)
	No	4181 (92.71)
EF (Mean ± SD)		48.20±8.41
HR (Mean ± SD)		70.71±4.59

Walking, Oil intake, Milk intake, Fruit intake, Salad intake, Animal food, Yoga, Meditation and Stress Management was also observed. A significant change in tobacco consumption was observed from baseline median 2 to 0 at 5th year of follow up. Walking improves from median 2 to 6 at 5th year of follow up. Oil intake, the frequency was reduced from unlimited (median 3) to minimal (median 0) at 5th year of follow up. Milk intake was also reduced from unlimited (median 3) ; full cream

milk to minimal (median 0); skimmed milk at 5th year of follow up. Fruit intake was increased from median 2 to 6 days/week at 5th year of follow up. Salad intake was also increased from median 1 to 6 days/week at 5th year of follow up. The frequency of animal food intake was also decreased from median 2 to 0 with the range of 0-3. Adherence to the yogic exercise was also increased from 1 day /week to 5 days/week at 5th year of follow up. Similarly, adherence towards meditation practice was also

Table 4. Changes in Cardiac Risk Factors from Baseline to 1st year, 3rd year and 5th years of study follow-up

Variables	Baseline Mean ± SD	1 Year Mean ± SD	3 Year Mean ± SD	5 Year Mean ± SD	p-value
Cholesterol	175.43±44.82	128.97±47.72	134.0±30.06	144.78±47.83	<0.0001
Triglyceride	157.55±35.91	99.77±19.52	107.37±15.44	128.67±41.09	<0.0001
HDL/Cholesterol percentage	24.96±7.94	42.10±16.54	41.40±13.51	31.62±10.01	<0.0001
SBP	135.02±19.89	117.06±5.32	118.0±4.17	119.99±1.73	<0.0001
DBP	87.54±9.69	75.28±5.01	76.06±4.92	78.57±3.51	<0.0001
BSF	106.47±29.44	98.47±23.81	100.18±23.71	102.45±27.37	<0.0001
BSPP	140.88±66.50	128.97±47.72	130.28±45.93	135.57±56.63	<0.0001
BMI	25.71±3.90	23.98±4.34	24.40±4.12	24.62±4.01	<0.0001

Table 5. Changes in Cardiac Risk Factors (Median) from Baseline to 1st year, 3rd year and 5th years of study follow-up

Variables	Median Range Median	Baseline (Min-Max)	1 Year Median	3 Year Median	5 Year Median	p-value
Tobacco	0-3	2	0	1	1	<0.0001
Walking	0-7	2	6	5	4	<0.0001
Oil intake	0-3	3	0	1	1	<0.0001
Milk intake	0-3	3	0	1	2	<0.0001
Fruit intake	0-7	2	6	5	4	<0.0001
Salad intake	0-7	1	6	5	4	<0.0001
Animal food	0-3	2	0	1	2	<0.0001
Yoga	0-7	1	5	4	4	<0.0001
Meditation	0-7	2	5	4	3	<0.0001
Stress Level	0-3	3	1	1	2	<0.0001

Table 6. Changes in Clinical Parameters from Baseline to 1st year, 3rd year and 5th years of study follow-up

Variables	Baseline Mean ± SD	1 Year Mean ± SD	3 Year Mean ± SD	5 Year Mean ± SD	p-value
NYHA Angina Classification	3.08±0.56	2.34±0.62	2.42±0.68	2.45±0.70	<0.0001
Intake of drugs (Anti-Anginal)	4.36±1.35	2.95±0.65	3.12±0.58	3.82±1.20	<0.0001

Table 7. Changes in SHA Protection score from Baseline to 1st year, 3rd year and 5th years of study follow-up

Variables	Baseline Mean±SD	1 Year Mean±SD	3 Year Mean±SD	5 Year Mean±SD	p-value
Cholesterol	2.70±3.72	8.48±3.48	6.75±4.12	5.47±4.30	<0.0001
Triglyceride	1.80±2.42	7.46±2.64	6.17±2.50	4.44±2.26	<0.0001
HDL/Cholesterol percentage	2.69±2.52	7.02±3.03	6.49±3.51	4.69±3.12	<0.0001
SBP	4.94±4.85	9.94±0.71	9.98±0.37	9.97±0.46	<0.0001
DBP	3.56 ±1.96	7.36±2.49	6.97±2.44	5.71±1.75	<0.0001
BSF	6.74±3.61	7.60±3.63	7.58±3.67	7.56±3.69	<0.0001
BSPP	8.43±3.56	8.65±3.23	8.60±3.28	8.52±3.50	<0.0001
Tobacco Consumption	4.89±4.48	7.57±2.50	7.23±2.51	6.86±3.03	<0.0001
BMI	4.99±3.67	6.78±4.52	6.42±4.57	5.54±3.98	<0.0001
Walking	1.01±0.31	9.95±0.49	9.96±0.43	7.29±2.73	<0.0001
Oil intake	1.12±0.46	7.76±2.51	7.25±2.50	5.53±4.14	<0.0001
Milk intake	1.52±0.91	5.52±4.22	5.34±4.24	2.11±1.81	<0.0001
Fruit intake	3.73±1.90	9.85±0.90	8.97±2.08	6.64±2.71	<0.0001
Salad intake	2.79±2.02	8.58±2.27	6.25±2.17	5.93±2.28	<0.0001
Animal food	3.45±2.39	8.46±2.43	5.58±4.23	4.41±4.25	<0.0001
Yoga	1.11±0.70	7.00±2.48	5.91±2.27	5.34±2.00	<0.0001
Meditation	1.04±0.51	7.36±2.50	5.78±2.08	4.59±1.33	<0.0001
Stress Level	1.72±1.04	5.19±1.37	5.38±2.03	4.62±4.26	<0.0001
Total SHAP Score	56.68±13.53	140.60±15.62	126.69±14.09	104.13±14.55	<0.0001

Table 8. Changes in outcomes from baseline to 1 year, 3 year and 5 Year follow up follow-up with differences in within and between groups over time

Variables	Mean change from Baseline to 1 Year of follow up	Mean change from Baseline to 3 Year of follow up	Mean change from Baseline to 5 Year follow up	p-value
Cholesterol	46.45 (44.52-48.38)	41.43 (39.84-43.01)	30.65(28.9-32.4)	<0.0001
Triglyceride	57.7 (56.58-58.95)	50.17(49.03-51.32)	28.88 (27.28-30.48)	<0.0001
HDL/Cholesterol %	-17.14 (-17.68- - 16.61)	16.44(-16.90 - - 15.98)	-6.65 (-7.01 - - 6.30)	<0.0001
SBP	17.96(17.36-18.55)	17.01(16.42-17.6)	15.02(14.44-15.60)	<0.0001
DBP	12.25 (11.93-12.58)	11.47(11.15-11.79)	8.9(8.66-9.26)	<0.0001
BSF	8.01 (7.46-8.54)	6.29(5.77-6.80)	4.02(3.56-4.47)	<0.0001
BSPP	11.9(10.94-12.86)	10.59(9.64-11.55)	5.30(4.64-5.96)	<0.0001
Tobacco Consumption	0.67 (0.64-0.71)	0.62(0.57-0.64)	0.51(0.48-0.55)	<0.0001
BMI	1.68 (1.60-1.76)	1.31(1.23-1.39)	1.09(1.01-1.17)	<0.0001
Walking	-4.01(-4.02- - 3.99)	-3.31(-3.33- - 3.29)	-2.46(-2.51- - 2.42)	<0.0001
Oil intake	1.94 (1.91- 1.96)	1.84(1.81-1.86)	1.41(1.37 - 1.45)	<0.0001
Milk intake	1.41(1.37-1.44)	1.35(1.32-1.39)	0.59(0.56-0.62)	<0.0001
Fruit intake	-3.47 (-3.29- - 3.24)	-2.21 (-2.23- - 2.17)	-1.43(-1.46- - 1.38)	<0.0001
Salad intake	-3.59 (-3.63- - 3.54)	-2.97(-3.02- - 2.93)	-2.25(-2.31 - - 2.19)	<0.0001
Animal food	1.63 (1.59-1.66)	0.96(0.92-1.01)	0.61(0.56-0.65)	<0.0001
Yoga	-3.74 (-3.77- - 3.71)	-2.98(-3.02- - 2.94)	-2.46(-2.50 - - 2.43)	<0.0001
Meditation	-3.45 (-3.47- - 3.42)	-2.45(-2.48 - - 2.41)	-1.23(-1.25- -1.21)	<0.0001
Stress Level	1.37 (1.34- 1.38)	1.31(1.27-1.34)	1.08(1.04- 1.12)	<0.0001

increased from 2 days/week to 5 days /week at 5th year of follow up. A significant improvement in stress management from excess (median 3) to a minimum (median 1) was observed at 5th year of follow up. The details of the results are given in table 5.

Effect of LMC in Clinical Parameters

A significant improvement in New York Heart Association (NYHA) angina classification was observed from baseline (3.08±0.56) to 5th year (2.34±0.62) of follow up with $p < 0.0001$. The number of drugs used for angina and heart disease was also decreased from baseline (4.36±1.35) to 5th year (2.95±0.65) of follow up after LMC. The detail of the results are given in table 6.

Impact of LMC using the SHS Wheel in CHD patients

A significant improvement in SAAOL Heart Attack (SHA) protection score was observed from baseline to 5th year of follow up. Cholesterol score was increased from 2.70±3.72 (baseline) to 8.48±3.48 (5th year) and triglyceride score was also increased from baseline (1.80±2.42) to 5 years (7.46±2.64) follow up. A significant increment in HDL/Cholesterol percentage was observed from baseline (2.69±2.52) to 5th year (7.02±3.03) of follow up. SBP score was increased from baseline (4.94±4.85) to 5th year (9.94±0.71) of follow up and DBP score was increased from baseline (3.56±1.96) to 5th year (7.36±2.49) of follow up. A significant improvement in BSF from baseline (6.74±3.61) to 5th year (7.60±3.63) of follow up and BSPP from baseline (8.43±3.56) to 5th year (8.65±3.23) of follow up was observed. Tobacco consumption score was also improved from baseline (4.89±4.48) to 5th year (7.57±2.50) of follow up. BMI score was also improved from baseline (4.99±3.67) to 5th year (6.78±4.52) of follow up. Walking score also increase from baseline (1.01±0.31) to 5th year (9.95±0.49) of follow up. The Oil intake score was also improved from baseline (1.12±0.46) to 5th year (7.76±2.51) of follow up. The Milk intake score was also improved from baseline (1.52±0.91) to 5th year (5.52±4.22) of follow up.

A significant improvement in fruit intake score was observed from baseline (3.73±1.90) to 5th year (9.85±0.90) of follow up. The salad intake score was also increased from baseline (2.79±2.02) to 5th year (8.58±2.27) of follow up. Intake of animal food score was also improved

from 3.45±2.39 (baseline) to 8.46±2.43 (5th year) of follow up. A significant improvement in the yogic exercise was also observed from baseline (1.11±0.70) to 5th year (7.00±2.48) of follow up. Meditation score was also improved from baseline (1.04±0.51) to 5th year (7.36±2.50) of follow up. A significant improvement in stress management score was observed from baseline (1.72±1.04) to 5th year (5.19±1.37) of follow up. A significant improvement was observed in total SHA protection score from baseline (56.68±13.53) to 5th year (140.60±15.62) of follow up after LMC with $p < 0.0001$. The complete information about SHA protection scoring and clinical outcomes are given in table 7 and 8.

Means differences within and between group are in mean (95% Confidence Interval), a negative change indicates a fall on average from baseline to 1 year, baseline to 3 years and baseline to 5 years follow up. Determined repeated measures ANOVA within and between groups comparison and multi-variant analysis for significant change at $p < 0.05$.

Cost -effectiveness of treatment

Lifestyle intervention was observed cost-effective treatment method with intervention cost (2400 INR-3000 INR) as compared to CABG (1,50,000 INR-4,50,000 INR) and PTCA (1,20,000 INR-1, 60,000 INR) treatments. The median of intervention cost was 2400 INR at 1 year follow up, 2500 INR at 3rd year follow up and 3000 INR at the end of the intervention (overall median 2700 INR) on the other side cost of CABG was range from 1,50,000 INR to 4,50,000 INR (Median 3,00,000) and PTCA was range 1,20,000 INR to 1,60,000 (median 1,40,000 INR) was observed. Hence, lifestyle intervention is a cost-effective treatment method for CAD patients.

Clinical Assessment at the end of the study

Our study revealed that 98% of CAD patients avoided heart attack and other treatment options such as CABG and PTCA. Only 2% of CAD patients had the history of minor attacks and other health problems.

DISCUSSION

The purpose of this study was to determine the effectiveness of lifestyle modification counseling using the SAAOL Heart Safety wheel

on cardiac risk factors at the 1st, 3rd and 5th year follow-ups. The results of our study indicate the significant improvement in NYHA angina classification and reduced the number of medicines used to treat coronary heart disease patients. The SAAOL Heart Safety wheel was found an effective and reliable tool in the management and control of cardiac risk factors. A study done by Dean Ornish reported that CAD can be reversed and control through dietary changes, yoga, walk and meditation.¹⁴⁻¹⁵

Effect of LMC on Angina and medications

The present study showed a significant improvement in NYHA angina class and number of angina medicines was also reduced from baseline to 5th year follow up. Similarly, a study done by Yogendra *et al* supports the present study and showed a significant improvement in functional class (NYHA II to NYHA I), angina symptoms, and reduce the consumption of the nitrate tablets (medicines) after lifestyle modification and yoga practice.¹⁹

Effect of LMC on cardiac risk factors

The results of the present study showed significant improvement in lipid profile (total cholesterol, triglyceride, HDL/cholesterol ratio), from the 1st follow up to 5th year follow up after lifestyle intervention.

A similar study done by Ibhar *et al* showed a significant decrease in total cholesterol from baseline to 2 year follow-up.²⁰ Similarly, studies done by Browning *et al* showed significant improvements in triglycerides, HDL, LDL cholesterol HbA1c, and BMI, in the intervention group after receiving a motivational intervention counseling.²¹ Likewise, Yogendra *et al*¹⁹ found statistically significant changes in the serum total cholesterol, triglyceride and LDL cholesterol after receiving educational counseling regarding disease, diet, and exercise for three months.¹⁹ The role of healthy and balanced diet in lipid metabolism cannot be undervalued, and it was clearly recognized by Sasakabe *et al* in his study, they found that a significant reduction in LDL-C and a significant increase in HDL-C, by accepting a low fat and carbohydrate diet for three months.²² These findings indicate an improvement in health status, quality of life, and decreased the risk of cardiovascular other complications. These findings are similar to the present study, with the decrease in

carbohydrates consumed together, and an increase in the frequency of vegetable consumption possibly accounting for these improvements. Another study on a heterogeneous group of patients with hypertension, CAD, DM, and a variety of other illnesses using lifestyle education program based on yoga, Manjunatha S *et al.* reported that fasting plasma glucose, serum total cholesterol, LDL, VLDL, the ratio of total cholesterol to HDL and triglycerides were significantly lower and HDL was significantly higher on the 5th Year of the lifestyle educational course compared to the first day of the course.²³ The results of the present study showed a significant reduction in BMI from baseline to 5th year of study follow up.

The results of the present study showed significant improvement in systolic and diastolic blood pressure from baseline to 5th year study follow up. A randomized clinical trial done by Maruthur *et al* showed a significant reduction in cardiovascular risk factors and blood pressure after a 1-year telephonic intervention counseling.²⁴ The authors reported a significant reduction in blood pressure similar to our study regarding the decline in hypertension in the study participants. Studies by Balducci *et al*²⁵ found that with a significant reduction in SBP and DBP in the experimental group after following 12 months aerobic and resistance exercise program. Similar results were described by Ades *et al*²⁶ after following a six-month diet and exercise intervention where there was a slight decrease in SBP, but a statistically significant decrease in DBP. A 12 months exercise program, conducted by Balducci *et al*²⁵ testified decreases in SBP and DBP from baseline to 12 months in both the control and experimental groups, although the greater decrease had been observed in the experimental group for both SBP and DBP. A study done by Sasakabe *et al* reported that a statistically significant decrease in SBP and DBP after adopting a low-carbohydrate diet.²²

The results of the present study showed significant improvement in body weight and BMI from baseline to 5th year study follow up. In A study done by Backer *et al* showed similar and significant decrease weight and BMI in the patients with a history of CVD by following structured lifestyle intervention program.²⁷ In a recent study by Emerenziani *et al* found a significant decrease in BMI in the experimental group and no change

in the control group after adhering 3 month aerobic exercise program.²⁸ A study by Ornish *et al*¹⁴ showed a significant reduction in body weight of CHD patients in the intervention group.

A significant improvement was observed in BSF and BSPP from baseline to 5th year of study follow up. The study results conclude that lifestyle modification counseling can give significant and beneficial impact on blood sugar levels. Studies done by Oldroyd *et al* and Ibrahim *et al* reported a decrease in the blood sugar levels after lifestyle interventions in at 1 year to follow up.²⁹⁻³⁰ In the present study, we found similar results, i.e. a decrease in blood sugar levels in participants. Studies done by Greaves *et al* found the significant reduction in blood sugar levels, insulin resistance, anti-diabetic medicines and body weight through diet and physical activity interventions.³¹

The results of the present study showed the significant reduction in tobacco consumption from baseline to 5th year of study follow up. There was a statistically significant reduction in tobacco use at three and six months in the study group as compared to the control group.

The present study showed a significant improvement in walking and functional capacity from baseline to the 5th year of study follow up after following Saaol safety wheel. A randomized controlled trial done by Thomas *et al* demonstrated that physical activity like walking can delay the progression of cardiovascular risk factors, impaired glucose tolerance when combined with dietary changes. The significant Improvements in cardiovascular risk factors, cardiorespiratory fitness, blood pressure, insulin resistance glycemic control, blood lipid profile, and decreased stress, anxiety, depression and chronic medication dosages in CHD and other chronic disease patients after adhering regular walk and physical activity is documented.³²

A study done by Franciosi *et al* shown that patient with CHD and T2DM who reported walking for at least two hours per week had a 39% lower all-cause mortality rate than those who reported no walking.³³ A significant reduction in animal food intake, oil intake, and milk intake was observed in study participants from baseline to 5th year of study follow up. It is proven that the vegetarian diet is healthful and effective in weight management, glycemic control, reversing

atherosclerosis, decreasing blood lipids, blood pressure and have favorable effects on diabetes, cardiovascular problems, obesity and other chronic diseases. The vegetarian diet is effective in the prevention and treatment of CHD and provides metabolic and cardiovascular benefits.

A significant improvement was observed in fruit and salad intake from baseline to 5th year study follow up. The results of the present study are similar to study by Chandalia *et al*³⁴ who found that the intake of a high fibrous diet shown 10 % improvement in glycemic control, 12 % improvement in insulin sensitivity and an about 9% decrease in lipid levels. A meta-analysis by Wu *et al* provided strong evidence that regular intake fibrous diet significantly reduces the risk of developing CHD, T2DM and other complications.³⁵

It is validated the association between fruit and vegetable consumption and the risk of coronary heart disease using the nurses prospective health study and the health professionals follow-up cohort study.

A significant improvement was observed in yoga practice adherence from baseline to 5th year of study follow up. At baseline, there were very few patients practicing yoga asana, but after receiving education through yoga teacher most of the patient were adhere to yoga.

McCaffrey and Rao *et al* reported that yoga practice is helpful in weight management, waist-hip ratio, decrease cardiac risks, stress reduction, and quality of life of patients. The result of a study showed significant decreases systolic and diastolic blood pressure and heart rate, after Yoga. It is documented that yoga improves the immune system with enhanced immunoglobulin A and natural killer cells (NKC) in stressed people. In most of the clinical studies, modifiable CAD risk factors are heart rate, blood pressure, lipid profiles, and body mass index.³⁶⁻³⁷

A significant improvement in meditation adherence was observed in CHD patient from baseline to 5th year of study follow up. Studies done by Gotink *et al* found, in a recent systematic review and meta-analysis of systematic reviews, using standardized meditation program significantly improvement in depression symptoms, anxiety and stress, improving life quality and physical functioning.³⁸ In a study by Rosensweig *et al* observed an improvement in glycemic control,

depression, anxiety and psychological distress after following one month meditation program. A study conducted by Keyworth *et al* found a significant improvement in glycemic control, sleep, relaxation, and better acceptance of the disease.³⁹⁻⁴⁰

Limitations of the study

There is no standard published tool to evaluate the holistic model adherence score of the participants besides only self-developed questionnaires and score was documented. This study was lacking the control group, which was the major drawback of the study design. Hence, there is a requirement of further multi-centric randomized control study with a larger population in the different region of India and abroad.

CONCLUSION

This study concludes that yoga-based lifestyle modification counseling through a holistic approach was effective in improving angina and cardiac risk factors. A significant reduction in the total number of medicines used for CHD was also observed in this study. This type of holistic approach may help to reduce the rate of cardiac events and heart attacks. There is further long-term multicentric randomized controlled trials are required for better clinical outcomes.

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