

Regression of Coronary Atherosclerosis through Healthy Lifestyle in Coronary Artery Disease Patients - Mount Abu Open Heart Trial.

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Abstract

Aims: To evaluate the efficacy of a unique healthy and happy lifestyle (HLS) program in regression of coronary atherosclerosis and reduction in cardiac events in an open trial.

Methods : One hundred and twenty three angiographically documented moderate to severe coronary artery disease (CAD) patients were administered HLS comprising of low-fat, high-fiber vegetarian diet, moderate aerobic exercise and stress-management through Rajyoga meditation. Its most salient feature was training in self-responsibility (heal+thy) and self-empowerment through inner-self consciousness (swasth; swa=innerself, sth=consciousness) approach using Rajyoga meditation. Following a seven day in-house sojourn, patients were invited for six month follow-up for reassessment and advanced training. At the end of two years, all patients were asked to undergo repeat angiography.

Results: Three hundred and sixty coronary lesions were analysed by two independent angiographers. In CAD patients with most adherence, percent diameter stenosis regressed by 18.23 ± 12.04 absolute percentage points. 91% patients showed a trend towards regression and 51.4% lesions regressed by more than 10 absolute percentage points. The cardiac events in coronary artery disease patients were: 11 in most adherence, and 38 in least adherence over a follow-up period of 6.48 yrs. (risk ratio; most vs least adherence: 4.32; 95% CI: 1.69-11.705; $P < 0.002$).

Conclusion : Overall healthy changes in cardiovascular, metabolic and psychological parameters, decline in absolute percent diameter coronary stenosis and cardiac events in patients of CAD were closely related to HLS adherence. However, more than 50% adherence is essential to achieve a significant change.

Keywords: Healthy lifestyle, coronary artery disease, Rajyoga meditation, vegetarian diet

INTRODUCTION

Coronary artery disease (CAD) is a major cause of premature mortality and disability in both developing and developed nations^{1,2}. Over the last three decades, progress in coronary artery bypass grafting (CABG) and percutaneous interventions (PCI) has improved the prognosis of CAD³, but has not been able to address the basic issues of aetiopathology, providing merely palliative relief at a high cost⁴⁻⁶. CAD is now widely recognized as a lifestyle disease; hence its management should be lifestyle modification⁷. The lifestyle intervention studies in small number of CAD patients have shown that dietary modifications, physical exercise and stress relaxation techniques can curtail progression of coronary blockages and decrease the frequency of angina and

heart attacks⁸⁻¹⁰. In the lifestyle heart study⁸, a combination of an extremely low fat diet, exercise, stress management and yoga reduced progression of atherosclerosis, but the low fat regime was unnecessarily very rigid and difficult to follow. Recent investigations have provided convincing evidence that the present prevalent outer self (body, role, material) conscious approach can lead to activation of psychosocial factors like depression, anxiety, anger, hostility, isolation and chronic life stress which can contribute significantly towards development and promotion of CAD by encouraging adoption of unhealthy lifestyle behaviours like smoking, atherogenic diet and sedentary habits¹¹⁻¹⁶. Besides activating the sympatho-adreno-medullary system these psychological factors can also activate endothelial dysfunction and platelet

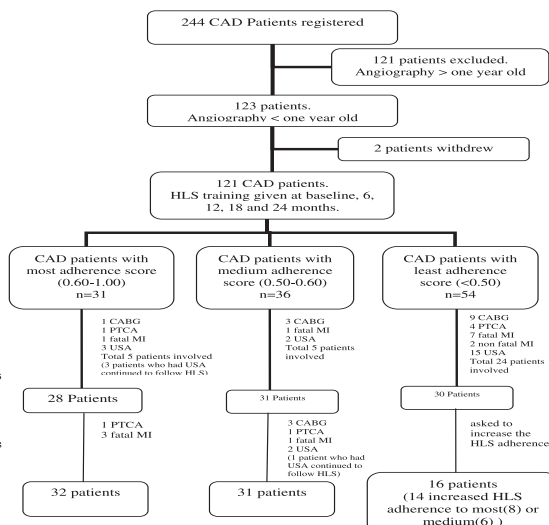
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activation and can become major impediment in modification of the acquired aberrant lifestyle¹⁷⁻¹⁹.

The objective of the present study has been to develop a user friendly HLS program and to determine its efficacy in regression of established CAD. The unique feature of this program is that it focuses on self-responsibility and self-empowerment as the basis for regression of coronary atherosclerosis and reduction in coronary events through intensive information, education and counseling provided to patients of CAD. The aim of this publication is to highlight the features of the HLS program and to present the findings of this pilot study in angiographically documented CAD patients.

MATERIALS AND METHODS

Two hundred and forty four angiographically documented CAD patients were invited to participate in this study at Global Hospital & Research Centre, Mount Abu, India. The inclusion criteria were: angiographically documented stable CAD with more than 50% stenosis in at least one major epicardial vessel, coronary angiography having been performed within the last 6 months to one year; and patients for whom CABG or PCI were not considered due to poor anatomy, those unwilling to undergo CABG/PCI and left ventricular ejection fraction(LVEF) >20% and without LVF. The exclusion criteria were: another co-existent life-threatening illness, acute coronary syndrome or significant left main disease(e”50%). Of the 244 invitees, 123 CAD patients, 35-72 years, with chronic stable angina fulfilled all the criteria and were registered for the study. Out of 123, 2 patients did not attend the first six-month follow-up study(Figure-1). **Design of the Mount Abu Open Heart Ttrial**



The trial was initiated before the results of major statin trials were published, and none of the patients was receiving lipid lowering medications. One hundred and twenty one patients were on nitrates, 114 on anti-platelet agents, 78 on beta blockers, 56 on calcium channel blockers and 51 on ACE inhibitors.

These patients served as their own control and their baseline characteristics are shown in Tables 1 & 2. Sixty seven percent patients had a documented history of myocardial infarction, 34% had diabetes mellitus, 60% had hypertension, 45% had a history of dyslipidaemia, 40% had a history of smoking, 53% had education up to high school or less and 50% patients were from the middle or low middle socio-economic group. On coronary angiography, 49% had triple vessel disease, 36% had double vessel disease and only 17% patients had single vessel disease. A total of 306 coronary lesions were taken at baseline for analysis. Average percent diameter stenosis at baseline was 65.40±14.11 (Mean ± SD) and the average number of lesions was 4.36±2.49.

Groups, limited to 10-20 patients and their spouses, stayed in-house for seven days. On the first day, assessments were made on baseline symptom score, drug score, exercise tolerance, glycaemic status, lipid profile and psychological profile. The next step was detailed information, education, training and counseling about the aetiopathology of CAD and the importance of adopting and maintaining a healthy lifestyle. Daily group support sessions encouraged patients to curtail isolation and integrate happily with each other. The spouses were also motivated to follow the HLS program as a moral support.

On sixth day of training, the study parameters were reassessed. Each patient and spouse interacted with counselors: clinician, psychologist, Rajyoga meditation teacher, dietician, exercise expert, ‘Dilwalas’ (CAD patients following HLS Program) for overall risk factor modification and treatment advice. They were provided with hand-outs, written material, commentaries and cassettes about pathogenesis of CAD, diet, exercise, Rajyoga meditation and the HLS Program concept. Medications for angina, hypertension, diabetes, antiplatelet agents, etc. were continued and modified as per standard clinical guidelines. All volunteers received follow-ups on intention-to-treat basis. After 7-day sojourn, subjects were allocated to a Brahma Kumaris Rajyoga centre within their vicinity for daily follow-up. Compliance to the program was assessed using a 3 tier system. 1. Ten-point self – assessment adherence chart. Each lifestyle related issue was given a score of 0-10 to generate a quantitative score. A score of 10 indicated 100% adherence while 0 indicated complete lack of adherence. 2. Monthly report from the regional coordinator and 3. Strict evaluation of each patient was

individually done by the psychologist at 6 monthly follow-ups. Patients were motivated to achieve at least 75% adherence to open their coronary blockages. The study protocol was approved by the Institute's ethical committee, and written informed consent was obtained from every patient. An option for an angioplasty or bypass surgery was offered to all patients when required.

HEALTHY LIFESTYLE - CONCEPT

Four principles, intrinsic to Rajyoga, which underlie the program ethos are:

- i.) **Self-responsibility through self-empowerment:** The word 'healthy' is derived from two words; 'heal' + 'thy' i.e., to heal yourself. To heal oneself, one needs to be empowered by appropriate and proper information about heart, mind-body connection, psychological and conventional risk factors, stress-management, diet, exercise, sleep, substance abuse and usual medical care.
- ii.) **Self-awareness:** The Hindi word for healthy is 'swasth', which consists of *swa-*, meaning 'inner self', and *-sth*, meaning 'conscious', so the word 'healthy' could also mean 'inner self-conscious'. Outer self-consciousness (of body, role or material things, which are ever-changing and mortal) leads to instability and insecurity, which in turn leads to anger, anxiety, depression, type A behaviour, isolation and chronic life stresses. Conversely, inner self-consciousness (of spirit, which is enduring and immortal) leads to stability and security, which in turn leads to peace, love and happiness. So, by abstraction, a healthy lifestyle means an 'inner self-conscious lifestyle';
- iii.) **Multi-dimensionality:** The current medical approach addresses only one dimension, the physical body, which might explain why despite medical advancements the epidemic of CAD has not been curbed. A human being is not one-dimensional. Therefore, a new model of health, 'Soul-Mind-Body Medicine' (three dimensional healthcare) is called for. As per this new model, health is a dynamic process of harmony in flow of spiritual energy (knowledge of truth, purity, peace, love, happiness, bliss and power: of discretion, to judge, to withdraw, to pack up, to tolerate, to face, to accommodate, to cooperate), mental energy (Positive T.E.A.M.: thoughts, emotions, attitudes and memories) and physical energy (healthy diet, exercise, sleep and medication).
- iv.) **Biological clock / circadian rhythm:** When activities are in rhythm with one's biological clock, they reduce energy expense and stress, and prove beneficial for the health of mind, intellect and body.

All four principles should be sustained as far as possible in

daily living.

The three major components of HLS program were:

- i.) **Stress-management through Rajyoga meditation:** Stress is defined as mental state in which the internal and external pressures exceed the inner strength (coping mechanism) leading to sympathetic over activity and release of stress hormones which in turn leads to vicious cycle of mental dis-ease and physical dis-ease. Inner strength can be increased by Rajyoga. Rajyoga word has been derived from Raja meaning king and yoga meaning union between Soul (spiritual energy) and Supreme Soul (ocean of spiritual energy). Rajyoga meditation harmonizes spiritual, mental and physical energy, thereby increasing inner strength to lead a stress-free and healthy life. It enhances individual's power of determination to manage and practice positive thoughts, emotions, attitudes, memories and adhere to healthy diet, exercise, sleep, medication and cessation of smoking. Expert Rajyoga teachers from Prajapita Brahma Kumaris Ishwariya Vishwa Vidyalaya Mount Abu, taught Rajyoga meditation in three different stages. During Stage-I (Inner self empowerment), patients were provided knowledge about Soul and Supreme Soul and trained to forge a link with the Supreme Soul to draw spiritual energy. This was followed by sessions of training in opening and healing the mind and opening the coronary blockages. In Stage-II of opening and healing the mind, patients were made to understand the role of non-physical factors like depression, anger, cynicism, hostility, ego, jealousy, hurry, worry, anxiety, fear, isolation, lack of social and emotional support, job and family stress etc, in the development of CAD; as these negative traits are acquired from the environment and are not part of the original inner self. They were trained to inculcate the positive mental energy thereby enhancing willpower to adhere to healthy and happy lifestyle program. In stage-III of opening the coronary blockages by Rajyoga meditation, they were asked to focus the inner, radiant spiritual energy on various organs of the body including the stenosed arteries for regression of the disease. A meditation commentary was provided to guide the mind in a positive direction. They were encouraged to maintain an inner self (soul) conscious mental state even while engaged in day-to-day work activities.
- ii.) **Low fat, high fiber vegetarian diet:** The essential components of diet program were: what? (low fat, high fiber vegetarian), when? (as per biological clock) and how? (proper chewing in inner self conscious state). Diet consisted of low fat mostly PUFA and MUFA providing 15% of the calories, cholesterol intake restricted to less

than 50mg/ day; soluble fiber about 50gms/ day, from 15gm psyllium husk/day, oat bran, fruits, vegetables, sprouted seeds, beans, salads etc; complex carbohydrates providing about 65% of the calories; proteins 1gm/kg body weight from soyabean and other vegetarian sources; antioxidants from sprouted seeds, fresh fruits, vegetables and nuts.²³ Beneficial effects of the prescribed diet were explained both to the patients as well as their spouses by audio-visual means and practical demonstration sessions by the experts. The spouses were given the recipes of the diet used and also taught the cooking methods. Smaller and more frequent meals were provided. Diet was served in silence with light music played to enhance the quality of environmental ambience. Diet charts were also provided to each patient.

iii.) Moderate aerobic exercise: Patients were individually prescribed brisk walk for 30-45 min in the morning after the sun rise and 30 min of stroll during the evening before sun set according to their baseline exercise tolerance. They were trained to reach a target heart rate of 60-70% of their maximum predicted heart rate(MPHR) based on the level of physical conditioning.²² Initially all patients were made to walk to achieve 50% of MPHHR and then gradually build up over a period of one month or so to 60% and then to 70% of MPHHR, according to their health status. In this study, (61%) patients had a history of documented myocardial infarction and many patients had undergone baseline coronary angiography without a baseline stress test. Exercise tolerance was measured by requiring them to walk at a stretch to achieve 60-70% MPHHR or ≥ 110 steps/minute before developing symptoms, e.g. angina or dyspnea (observed and measured walk at baseline). The exercise routine included warming-up period of 5 min, walking for 20-35 min, and cooling down period of 5 min. They were advised to walk in silence (inner self conscious state) and avoid walk after the meals or during extreme cold or hot climatic conditions.

FOLLOW-UP

Patients participated in daily support sessions, of 30-45 minutes, at their local Brahma Kumaris Rajyoga centers. To ensure proper adherence, weekly group support sessions facilitated by Regional co-ordinators and Rajyoga teachers addressed their day-to-day challenges. Every month the CAD project team visited three tertiary medical centers in Ahmedabad, Delhi and Mumbai for follow-up, assessment of clinical status and program adherence. Those inaccessible were sent questionnaires with self-addressed, stamped envelopes. At 6-monthly intervals, patients and their spouses

were invited for follow-up and reassessment. The study parameters were repeated at 6, 12, 18 and 24-month intervals, and patients were advised to have repeat angiography after two years of follow-up. These patients were monitored for cardiac events until 30 June, 2006.

Psychological Status: Psychological tests were administered during the morning hours, using a battery of standardized psychological inventory. Anxiety was measured using the IPAT Anxiety Scale questionnaire²¹. Depression was evaluated using the Minnesota Multiphasic Personality Inventory (MMPI) questionnaire²². Anger was measured by MMPI-2 anger content scale.¹⁵ Well-being was evaluated using a questionnaire on general health, quality of sleep, mental condition and feelings towards peers and superiors. The total score of subjective well-being was calculated using a four-point scale.

Blood biochemistry: Blood glucose, serum cholesterol, triglyceride and HDL-cholesterol were estimated using commercially available kits using RA 50, semiautomated clinical chemistry analyzer (Bayer Diagnostics, India). Glucose kits were obtained from Bayer Diagnostics, India. Total cholesterol, HDL cholesterol and triglyceride kits were obtained from M/S Ranbaxy Diagnostic, India. The LDL-cholesterol and VLDL-cholesterol were calculated using Friedewald's formula.

Coronary angiography: Baseline and repeat coronary angiography reels/CD's were coded to blind group allocation and to angiography sequencing (baseline or repeat). A panel of two independent angiographers analyzed the angiograms and selected the views in which the blockages were best seen. All 100% occluded lesions, instent lesions and non-matching lesions were excluded. An electronic Digimatic Calliper (Mitutoyo, Japan) was used to quantitatively assess the percent diameter stenosis. Trends towards regression/progression were calculated by the percentage of patients who showed overall regression/progression in repeat angiographies as compared to baseline coronary angiographies.

Statistical analysis: The data was analysed by an independent Biostatistician using SPSS 9 software. All data is presented as Mean \pm SD. To analyse changes in coronary lesions, percent diameter stenosis was taken as the primary dependant variable. The mean and variance were calculated for quantitative parameters and frequency with percentage for quantitative data. The comparison between two groups was done using paired 't' and unpaired t-tests whereas for comparisons between three groups ANOVA was used. To compare the proportions between different groups, the Chi square test was used and to compare the scores, non-parametric tests were used. The baseline score data among three groups was

vs least adherence $p < 0.022$). LDL cholesterol levels decreased by 8.5% at day 7 and decreased further at 6 months (13.8%), 12 months (17.7%) and at 24 months (10.16%) of follow-up (overall $p < 0.001$). A highly significant decrease in LDL levels was observed in patients with most adherence (16.87%, $p < 0.001$) compared to an insignificant decrease in patients with least adherence (most vs least adherence $p < 0.041$). HDL cholesterol levels increased by 3.6% at day 7 and 5.6% at 2 years ($p > 0.05$). Patients with most adherence recorded 6.4% ($p > 0.05$) increase in HDL levels at 2 years compared to 2.06% decrease in patients with least adherence (most vs least adherence $p > 0.05$). Triglyceride levels decreased by 13.4% at day 7 and this decrease was maintained at 6 months (14.1%), 12 months (15.6%) and at 24 months (13.07%) follow-up (overall $p < 0.001$). A highly significant decrease (30.1%, $p < 0.001$) was observed in patients with most adherence at 2 years compared to insignificant decreases in patients with least adherence (11.29%) ($p > 0.05$). The average LDL/HDL ratio decreased at 7 days (11.6%), which further decreased by the 6-month (16.3%), 12 month (21.4%) and 24-month (16.4%) follow-ups (overall $p < 0.001$). A highly significant decrease (25.79%, $p < 0.002$) was observed in patients with most adherence compared to an insignificant decrease (2.14%) in patients with least adherence.

Glycaemic control: Blood glucose and glycosylated hemoglobin tended to decline but the change was not statistically significant ($p > 0.05$).

Clinical parameters (Table 2)

NYHA Functional Class (Symptom Score): The average NYHA functional class significantly reduced by 28.3% by day 7 of follow-up, and further reduced by 57.2% by 24-month of follow-up (overall $p < 0.001$). Patients with most adherence had a highly significant reduction by day 7 (28.07%, $p < 0.01$) itself whereas it took patients with least adherence two years to reach a reduction of 27.9% ($p < 0.0001$).

Drug score (Number of 10mg nitrate tablets /day): The average drug score was reduced by 31.7%, at day 7 and 58.2% by the 24-month follow-up (overall $p < 0.0001$). A highly significant reduction in the drug score (35.37%, $p < 0.0001$) at day 7, and 89% reduction ($p < 0.0001$) at two years, compared to only 19.1% ($p < 0.004$) reduction at two years in the least adherence group ($p < 0.0001$). 61.3% patients with most adherence were off the nitrate therapy at two years.

Exercise tolerance: In this study, 81(66%) patients had a history of documented myocardial infarction, so many of them had undergone baseline coronary angiography without a prior exercise stress test. The average exercise tolerance at baseline 0.36 ± 0.46 km, increased by 210.80%, 378.37%, 448.00% and 540.00% by day 7 and 6, 12 and 24-month

respectively (overall $p < 0.001$). Patients with most adherence registered 897.29% increase in exercise tolerance at the end of 2 years ($p < 0.0001$) compared to patients with least adherence where it increased by 212.50% ($p = 0.000$).

Left Ventricular Ejection Fraction (LVEF): The average LVEF at baseline 46.51 ± 11.94 did not change significantly at the end of 2 years, but in patients with most adherence the LVEF increased by 8.24% ($p < 0.021$). In contrast, in patients with least adherence, the average LVEF reduced by 11.94% ($p < 0.009$).

Angiographic changes (Table 4)

Seventy three (76.04%) patients who had completed two years of follow-up underwent check-angiography at the end of two years. A total of 306 out of 362 lesions (50 lesions which were 100% occluded, and 6 instent lesions were excluded) were analysed. At baseline, there was no significant difference in any measure of lesion severity amongst patients with most, medium or least adherence.

The average percent diameter stenosis decreased by 6.10 absolute percentage points at 2 years ($p < 0.003$); i.e., a 7.06% relative improvement. Overall, HLS Program adherence was strongly related to changes in percent diameter stenosis of coronary artery lesions in a "dose response manner". In patients with most adherence, average percent diameter stenosis regressed from $70.06 \pm 8.09\%$ to $50.00 \pm 13.84\%$ i.e. a regression of 18.23 ± 12.04 absolute percentage points (29.03% relative improvement; $P < 0.0001$). In patients with medium adherence the average percent diameter stenosis regressed from $64.64 \pm 12.36\%$ to $52.78 \pm 17.48\%$ i.e. a regression of 11.85 ± 11.16 absolute percentage points (19.10% relative improvement; $p < 0.0001$). In contrast, in patients with least adherence, the average percent diameter stenosis progressed from $62.47 \pm 18.51\%$ to $73.03 \pm 17.53\%$ i.e. a progression of 10.56 ± 13.18 absolute percentage points (23.03% relative worsening; $p < 0.0001$). Overall, 63.01% patients showed trends towards regression of coronary atherosclerosis. In patients with most adherence, 90.91% showed trends towards regression of coronary atherosclerosis. In contrast in patients with least adherence, only 12% (3 out of 25) patients showed trends towards regression ($p < 0.0001$).

The change in lesion severity was classified into progression (percent diameter stenosis increased ≥ 10 absolute percentage points), regression (percent diameter stenosis reduced ≥ 10 absolute percentage points) or no significant change (percent diameter stenosis showing a change < 10 absolute percentage points). Overall, 37.4% lesions showed regression of $> 10\%$ absolute percentage points. In patients with most adherence, 51.4% lesions showed regression of $> 10\%$ absolute percentage points as compared to only 6.12%

lesions in patients with least adherence (overall Chi-square 102.57; $p < 0.001$)

Table 4: Changes in coronary artery lesions as per program adherence. Value are Mean \pm SD.

	OVERALL ADHERENCE	p	Most adherence	p	Medium adherence	p	Least adherence	P most vs. least adherence
% Diameter Stenosis								
No. of patients	73		22		26		25	
No. of lesions	306		102		118		98	
Baseline	65.40 \pm 14.11		70.06 \pm 8.09		64.64 \pm 12.36		62.47 \pm 18.51	
24 m	59.13 \pm 19.35		59.00 \pm 13.84		52.78 \pm 17.48		72.03 \pm 17.53	
Absolute change at 24 m	6.20 \pm 17.23		10.23 \pm 12.04		11.85 \pm 11.36		-10.56 \pm 13.18	
Relative change at 24 m	7.06 \pm 35.04		29.03 \pm 15.12		19.10 \pm 20.22		-23.03 \pm 38.35	
Trends in % Diameter Stenosis								
Progression	No. of patients 21 28.77		0 0.00		2 7.69		19 76.00	
No change	No. of patients 6 8.22		2 9.09		1 3.85		3 12.00	
Regression	No. of patients 46 63.01		20 90.91		23 88.46		3 12.00	
Overall Chi Square = 46.5, $p < 0.0001$								
Trends in Coronary Lesion Severity								
Progression	No. of lesions > 10% absolute change 40 12.60		1 3.20		6 5.08		33 33.68	
No change	No. of lesions > 10% absolute change 159 50.00		36 45.40		64 54.24		59 6.00	
Regression	No. of lesions > 10% absolute change 119 37.40		65 51.40		40 40.68		6 6.12	
Overall Chi Square = 102.57, $p < 0.0001$								

Determinants of CAD regression (Table 5)

Univariate analysis showed significant correlation between CAD regression and decrease in body weight ($P < 0.006$), triglycerides ($p < 0.03$), exercise ($p < 0.007$) and Rajyoga meditation ($p < 0.0001$). On multivariate analysis changes in body weight and lipid parameters were not independent predictors of CAD regression while management of psychosocial stressors through Rajyoga was found to be an independent predictor of CAD regression (OR: 347.73; 95% CI: 2.63-45,822; $p < 0.018$).

Table 5: Univariate and Multivariate analysis of various parameters in regression of CAD

	Odds Ratio	Univariate Analysis 95% CI	P	Odds Ratio	Multivariate Analysis 95% CI	P
WT_d \geq 3.0	8.71*	1.81 - 41.76	0.006	12.96	0.43 - 386.4	0.139
Tc_d \geq 15.8	2.10	0.69 - 6.37	0.190	0.07	.0009 - 6.28	0.252
Ldl_d \geq 11.0	2.18	0.74 - 6.40	0.155	0.52	.0071 - 38.17	0.766
Hdl_d \geq 0.9	2.97	0.98 - 9.03	0.054	2.47	.0728 - 84.07	0.614
Tg_d \geq 29.1	3.90*	1.13 - 13.37	0.030	144.22	.966 - 21533	0.051
Exercise \geq 60%	4.69*	1.52 - 14.43	0.007	0.07	.0006 - 9.55	0.295
Diet \geq 60%	7.08*	2.23 - 22.44	0.0009	3.72	.096 - 144.61	0.481
Rajyoga \geq 40%	164.0*	17.94 - 1498	0.0000	347.73*	2.63 - 45822	0.018
Program \geq 54%	72.0*	8.58 - 604	0.0001	33.38	.509 - 2188	0.100

Cardiac events (Table 6)

Data on cardiac events was obtained from all 121 patients over a mean follow-up period of 6.48 \pm 1.56 years (February 1998 - June 2006). At about 8 years follow-up, there were more events in the patients with least adherence (38 events for 54 patients, 0.37% events per person over 334.58 person years of observation; risk ratio least vs most: 4.32; 95% CI: 1.69-11.05; $p < 0.002$) compared to patients with most adherence (11 events for 31 patients; 0.225 events per person over 214.30 person years of observation). Patients with least adherence were found to be more likely to have undergone PCI (4 vs 2), CABG (10 vs 1) and to have been hospitalized for cardiovascular event (31 vs 5) than patients with most adherence. After eight years follow-up, all patients were informed of the results of the trial. In response, of the 30 patients with least adherence, 14 (47%) increased their

adherence (8 to most adherence and 6 to medium adherence). After eight years follow-up, there were 31 patients with most adherence, 31 patients with medium adherence and 16 patients with least adherence. Overall, it was observed that the number of cardiovascular events were strongly related to HLS program adherence in a "dose dependent manner".

Table 6: Cardiac events over a mean followup period of 6.48 \pm 1.56 (range 0.35 - 8.34 yrs). Values are Mean \pm SD

	Number of Coronary Events			Most, Vs., Least adherence		
	Most adherence n = 31	Medium adherence n = 36	Least adherence n = 54	Risk Ratio Most Vs. Least	95% CI	P
USA requiring hospital admission	3	4	15	3.59	0.95 - 13.59	0.06
Myocardial Infarction (Non Fatal)	1	2	2	1.15	0.10 - 13.26	0.909
Requirement of CABG	1	7	10	6.82	0.83 - 56.09	0.074
Requirement of PCI	2	1	4	1.16	0.20 - 6.73	0.869
Cardiac Mortality (Fatal MI)	4	2	7	1.005	0.27 - 3.75	0.994
Any event	11	16	34	4.32	1.69 - 11.05	0.002
No. of persons suffering cardiac events	9	11	28	1.96	0.76 - 5.02	0.163
Average event per person	0.225	0.305	0.370			
Average follow up in yrs (Range)	6.91 (0.96)	6.54 (1.37)	6.20 (1.88)			
Person years of observation	214.30	235.47	334.58			

DISCUSSION

Results from the present study suggest that CAD patients can be motivated to adopt the HLS program for a fairly long period of eight years of follow-up, while performing their routine activities outside the hospital framework. This program was found to be user-friendly, safe, flexible, and compatible with other treatments in the setting of advanced CAD, with a high degree of compliance. The primary end-point of this study was change in percent diameter stenosis. In patients with most adherence the average percent diameter stenosis decreased by 18.23 absolute percentage points (29.03% relative improvement), and in patients with medium adherence it decreased by 11.85 absolute percentage points (19.10% relative improvement), but it progressed in patients with least adherence. Cardiac events were also markedly decreased in patients with most adherence compared to patients with least adherence. However, more than 50% adherence to the prescribed HLS program is essential to achieve significant regression in percent diameter stenosis and in the number of cardiac events. The HLS program could modify psychosocial factors by significantly reducing anxiety, depression, anger and type A behaviour scores, improvement in healthy lifestyle and overall sense of well-being. The modification of psychosocial factors was reflected in better adherence to healthy lifestyle behaviour like cessation of smoking, adherence to prescribed diet and exercise schedules. Favourable highly significant changes were observed in NYHA function class, angina severity and frequency, drug score, and exercise tolerance by day 7 which were further favourably modified at different stages of follow up. The long-term reduction in NYHA functional class, nitrate requirement, and increased exercise tolerance is at par with what is achieved following coronary angioplasty or bypass surgery.

The improvement in various metabolic parameters in these patients may be due to the low-cholesterol, high-fiber vegetarian diet, physical exercise or Rajyoga meditation independently, or due to the synergistic effect of all three. An improvement in the various metabolic parameters after the present program are consistent with results found by other investigators who observed that a diet rich in fruits, vegetables and fiber can reduce the risk factors for CAD due to presence of a variety of phytonutrients²³⁻²⁵. The beneficial effects of exercise on coronary heart disease may be mediated through its effect on the cardiovascular system, on the musculoskeletal system and by modifying the various cardiovascular risk factors^{20,21}. Exercise can also increase vasodilatory prostaglandin and decrease levels of plasma rennin activity and blood viscosity²⁶.

The cardio-protective effects of Rajyoga meditation may be mediated through an interaction between the autonomic nervous system and the endocrine system²⁷⁻²⁹. In fact, in these CAD patients the administration of HLS also enhanced alpha activity of EEG and caused shift of autonomic balance towards relative parasympathetic predominance besides causing a marked reduction in secretion of stress hormones like epinephrine, nor-epinephrine and cortisol³⁰. Rajyoga is also a training in awareness which produces definite changes in perception, attention and cognition. During Rajyoga meditation, the practitioner remains awake and vigilant but the body enters a state of deep muscle relaxation. It also helps in building strong will-power for compliance to HLS program; as it teaches a holistic lifestyle modification, the benefits of which the participants begin to experience, within seven days of the intervention. Since Rajyoga meditation also enhances inner strength to lead a stress free and healthy life it might have caused marked reduction in psychological stressors and favourably modified, unhealthy behavioural patterns which in turn may be responsible for regression in coronary atherosclerosis and reduction in coronary events.

During the last 15 years, a number of randomized clinical trials using angiography have reported the effect of various interventions on the rate of progression/regression of coronary atherosclerosis in CAD patients^{8-10,31-36}. In the REVERSAL trial³¹ which focused primarily on effect of intensive compared with moderate lipid-lowering therapy and which used intravascular ultrasound (IVUS) has revealed that progression (2.7%) occurred in the Pravastatin 40 mg/day group and progression did not occur in the Atorvastatin 80 mg/day group at 18 months. In the Asteroid trial³² Rosuvastatin 40 mg/day for 24 months, significant reduction in percent atheroma volume (-0.79%) was observed using IVUS. Most of these studies reported better angiographic outcomes with greater reduction in LDL cholesterol because their treatment

groups produced reductions in LDL by 25% to 53% or more^{31,32}.

In the control groups of various lifestyle trials, e.g Lifestyle Heart trial^{8,9}, Manchanda et al¹⁰, Yogendra et al³⁴, STARS³⁶, SCRIP³⁷ and in patients with least adherence in our study, the average coronary lesion worsened at a rapid rate. In most of these trials, the treatment groups had no significant overall angiographic change, expressed in terms of percent diameter stenosis or minimum lumen diameter. In the SCRIP trial³⁷, the minimum lumen diameter worsened by 0.045mm per year in the control group, a rate similar to that seen in the control groups of lipid-lowering therapy trials^{31,32}. We recorded highly significant regression in coronary lesions with moderate reductions in LDL levels and a mild increase in HDL levels. Reductions in coronary atherosclerosis and cardiac events were strongly reflected in program adherence in a “dose response manner”.

The results of univariate analysis in these patients indicate that the angiographic changes were attributable to the decrease in weight, triglycerides, diet, exercise schedule and management of psychosocial stressors through Rajyoga meditation. The multivariate analysis showed that change in weight and lipid parameters are not independent predictors of CAD regression, but management of psychosocial stressors through Rajyoga was an independent predictor of CAD regression. The Rajyoga meditation also motivated CAD patients to adhere more to the diet, exercise, treatment schedules and smoking cessation.

LIMITATIONS OF THE STUDY

The present investigation is a feasibility pilot study to standardize the technique and determine its efficacy on regression of CAD in limited numbers of subjects. (1.) The study could not be blinded because of the nature of program. Independent angiographers, blinded to the group allocation and angiography-sequencing (pre or post), analyzed the angiograms. Highly significant regression in coronary atherosclerosis has been observed in this study but it is known that some lesions can regress & progress spontaneously, hence to validate these findings, a randomized trial, ABU – Healthy Heart Trial was undertaken in May 2000. (2.) All the recruited patients were advised repeat angiogram after completion of two years and followed up for clinical parameters and coronary events up to eight years. 73 CAD patients underwent repeat angiogram; rest did not have repeat angiography in spite of repeated request by the investigators. Some of the patients with most and medium adherence did not undergo repeat angiogram as they said they're already feeling better and hence were not interested in the same. Many patients with poor adherence refused

repeat angiogram because of more coronary events (n = 38) due to poor compliance to healthy & happy lifestyle. (3.) We had a three tier strict assessment of HLS program adherence score. More than 55% of patients had > 50% adherence to overall HLS program out of whom, 25.6 % had adherence of > 60% (most adherence) and 29.7% had adherence between 50% to 60% (medium adherence). 45 % patients had < 50% adherence probably because of our strict 3 tier (self assessment, regional coordinator and the psychologist) assessment of adherence score.

CONCLUSION

The HLS program is feasible, safe and compatible with other treatments in the setting of advanced coronary atherosclerosis with a high degree of compliance. The results from the study support the hypothesis that adoption and maintenance of this unique user-friendly healthy lifestyle program, which motivates patients to take up responsibility of their own health, on the basis of practicing inner self-consciousness can lead to a significant reduction in cardiac events, coronary atherosclerosis and effective control of symptoms like angina and breathlessness, a reduction of requirement for anti-anginal drugs, better control of hypertension and an improvement in exercise tolerance. A highly significant reduction in hospitalization for cardiovascular events was observed over a follow-up period of eight years.

A randomized, multi-disciplinary trial, the Abu Healthy Heart Trial, was initiated in May 2000 to further validate these findings.

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