



Improvement in Duke's Treadmill Score and VO₂Max using IRP Adjunct Therapy in Ischemic Heart Disease Patients- A Clinical Observational Study

Swati Ambulkar ^a, Pranit Ambulkar ^b *

^a Consultant Physician, Madhavbaug™ Cardiac Clinic, Hinjawadi Pune 411057 (India)

^b Consultant Physician, Dr. Ambulkar's Ayurveda Clinic, Wakad, Pune 411057 (India)

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ABSTRACT

Ischemic heart disease (IHD) remains a leading cause of cardiovascular morbidity and mortality worldwide, despite advancements in medical therapy. The limited efficacy of percutaneous coronary intervention (PCI) compared to conservative medicinal treatment, as demonstrated by the 'COURAGE' Trial underscores the need for alternative approaches to enhance the outcomes of conventional therapy. Ayurveda principles may offer a potential adjunctive therapy for improving the quality of life and clinical outcomes in IHD patients. A set of Ayurveda Panchakarma procedures termed as Ischemia Reversal Program (IRP) along with diet and lifestyle modification has shown encouraging results. 25 uncomplicated ischemic heart disease (IHD) patients on conventional aggressive conservative medicinal therapy were added on with IRP therapy and observed for three months. IRP included centripetal oleation with Amalaka Tail, thermal vasodilation with Dashmool Kashay, per rectal drug administration with Gokshuradya Kashay, High ORAC 1000 K Cal diet and basic walking exercise. Statistically significant improvement in ischemia status, Duke's trade mill scores (DTS), VO₂Max and BMI were observed with IRP over 90 days of trial. This is concluded that IRP therapy as an adjunct with conventional medicinal therapy is useful to improve ischemia status measures as DTS, cardiac endurance VO₂Max, quality of life and to reduce dependency on medications in in IHD patients. Further prospective research on larger population is warranted to validate these findings and elucidate the underlying mechanisms of action.

Keywords: IHD, ischemia, conservative, Ayurveda, IRP, Duke's trade mill score, VO₂Max, BMI

Introduction

Ischemic heart disease (IHD) remains a leading cause of cardiovascular morbidity and mortality worldwide¹, despite advancements in medical therapy. Out of all the cardiovascular deaths ischemic heart disease (IHD) contributes to 80% casualties. The limited efficacy of percutaneous coronary intervention (PCI) compared to conservative medicinal treatment, as demonstrated by the 'COURAGE' Trial², Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation A 15 year-long clinical trial on 2287 patient to evaluate efficacy of percutaneous coronary intervention against medicinal treatment underscores the need for alternative approaches to enhance the outcomes of conventional therapy. Ayurveda principles may offer a potential adjunctive therapy for improving the quality of life and clinical outcomes in IHD patients. A set of Ayurveda Panchakarma procedures termed as Ischemia Reversal Program (IRP)³ along with diet and lifestyle modification is being practiced at Madhavbaug™ Multidisciplinary Cardiac Care Clinics and Hospitals and good outcome in terms of improvement in medical parameters, cardiac endurance, risk factors alleviation and improvement in quality of life is being observed. Specifically, patients with urban sedentary lifestyle have shown very good results with adjunct of IRP therapy⁴. On this background, the present study was done as an observational study on 25 ischemic heart disease (IHD) patients residing in Rajiv Gandhi Infotech (IT) Park, Hinjawadi Pune area aiming to assess the impact of IRP therapy on key parameters including VO₂max, Duke's treadmill score, and BMI in IHD patients.

Objective

- To evaluate the effect of Ischemia Reversal Program (IRP) on: VO₂max, Duke's treadmill score, weight and BMI in IHD patients.
- to evaluate effect of Ischemia Reversal Program (IRP) Panchakarma therapy as an add-on to standard conservative drug therapy in ischemic heart disease patients.

Methods

This observational cohort study was conducted on 25 IHD patients residing in Rajiv Gandhi Infotech (IT) Park Hinjawadi Pune area, who were on conventional aggressive drug therapy for previous consecutive three months and attended out-patient departments (OPDs) at Madhavbaug multidisciplinary cardiac care clinic, Hinjawadi -Pune, and were willing to avail adjunct Ayurvedic conservative therapy to improve their disease status. Written consent for the same was obtained from the patients.

Inclusion Criteria:

- Diagnosed IHD patients, irrespective of the coronary artery disease status
- Stable inducible ischemia on cardiac stress test
- BMI range between 23 to 40
- Willing to give written consent for Ayurvedic conservative IRP therapy

Exclusion criteria

- Unstable angina
- Recent MI within one month
- any other complications, communicable diseases, severe illness, pregnancy, lactation, physical trauma, allergies to the therapy components, known contraindications to the therapy components

Components of IRP therapy:

1. Centripetal oleation: an oil massage with 100 ml 'Amalaka Taila' with specific centripetal pattern of strokes, pushing venous and lymph drainage from peripheries towards the heart. 30 minutes of procedure including oleation on upper and lower extremities, back, chest, abdomen and neck.
2. Thermal vasodilation: Steam bath for 20 minutes in a steam chamber with 'Dhashamula Kashaya', where humidity is 100% and temperature is 45°C. Head and neck are excluded from the steam bath using a specially designed cabinet.
3. Per rectal drug administration: 'Vasti' a kind of medicated enema of 'Gokshuradya Kashaya' 100 ml using a sterile syringe and a catheter.

Reverse™ Diet:

Diet replacement therapy with high ORAC, low carb- moderate protein- low fat, high fiber diet, around 1000 K Cal diet per day in divided doses.

Exercise included:

Brisk walking exercise 20 to 30 minutes according to the current time of ischemia (TOI) on TMT stress test, and walking speed as per the Targeted Heart Rate (THR) which is set to be 80% of maximum heart rate (MHR) [MHR = 200 – Age of patient in years] and exercise tolerance capacity as determined on TMT stress test.

Ayurvedic medicine included:

Plant based Ayurvedic medicine comprised of Terminalia arjuna, Tribulus terrestris, Curcuma longa, Emblica officinalis, Ricinus communis oil, twice a day in appropriate dose considering disease condition of the patient.

Treatment plan and schedule

It included 7 to 14 sittings of IRP Panchakarma therapy at a frequency of twice a week accompanied by 'Reverse™' diet therapy for two to three months and Ayurvedic polyherbal oral medications for three consecutive months. Exercise and lifestyle modifications were also advised for three consecutive months post enrolment in trial.

Assessment criteria

General vital parameters, BMI, ECG, TMT stress test, 2D Echo and relevant blood investigations were repeated time to time and variables were compared on the day of enrolment- day 1 and day 90 of the IRP therapy. The primary assessment criteria were Duke's trade mill score (DTS) whereas secondary assessment criteria were VO₂Max, Weight and Body mass index (BMI) Duke's trade mill score is calculated as Duke treadmill score = maximum exercise time in minutes-5 x ST segment deviation in mm -4 x angina index (where 0 = no angina, 1 = non-limiting angina, 2 = exercise limiting angina) ⁵.

Observations and Results

All 25 patients completed the study, and no adverse events were noted. The demographics of the participants are as follows.

Demographic Data

Table 1: Distribution of gender in study population

Gender	N	%
Male	15	60%
Female	10	40%

Table 2: Mean, Median and standard deviation in age of the study population

n=25		
	Mean + Std	Median
Age	58.48±10.06	60

After IRP therapy over three months, significant improvement was marked in VO_2 max from 12.57 + 5.73 to 24.94 + 5.19 ml/kg/min, (p =0.00) and Dukes score from -12.56 + 3.74 to -0.49 + 5.26, (p = 0.00) as compared to baseline in day 90. Patients categorized under DTS with Intermediate risk showed significant improvement in their mean weight from 71.69 to 67.44 kg, BMI from 27.43 to 25.99 kg/m², VO_2 max from 16.52 to 26.70 ml/Kg/min, and Duke’s score from -7.47 to 1.33. While patients categorized under DTS with severe risk showed appreciable improvement in their mean weight from 68.48 to 63.58, BMI from 25.65 to 23.63, VO_2 max from 11.04 to 24.26, and Duke’s score from -14.53 to -1.19 as compared to baseline and day 90. Dependency on concomitant standard medicines was reduced. Weight BMI and DTS showed statistically highly significant improvement with P<0.00.

Table 3: Statistical analysis of change in weight of patients

ANOVA: Single Factor						
SUMMARY						
Groups	Count	Sum	Average	Variance		
Weight Day 1	25	1734.45	69.38	106.97		
Weight Day 90	25	1616.46	64.66	86.97		
ANOVA						
Source of Variation	SS	df	MS	F	P-value	F crit
Between Groups	278.43	1	278.43	2.87	0.00	4.04
Within Groups	4654.54	48	96.97			
Total	4932.97	49				

Table 4: Mean, median and standard deviation in BMI

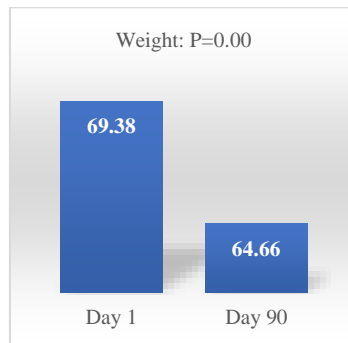
n=25	Day 1	Day 90	Day 1	Day 90
	Mean + Std		Median	
BMI	26.15+3.58	24.29+3.06	25.4	23.72

Table 5: Statistical analysis of change in BMI of patients

ANOVA: Single Factor						
SUMMARY						

Groups	Count	Sum	Average	Variance		
BMI Day 1	25	653.7	26.15	13.37		
BMI Day 90	25	607.27	24.29	9.77		
ANOVA						
Source of Variation	SS	df	MS	F	P-value	F crit
Between Groups	43.11	1	43.11	3.73	0.00	4.04
Within Groups	555.36	48	11.57			
Total	598.48	49				

Graph 1: Reduction in weight in patients



Graph 2: Reduction in BMI in patients

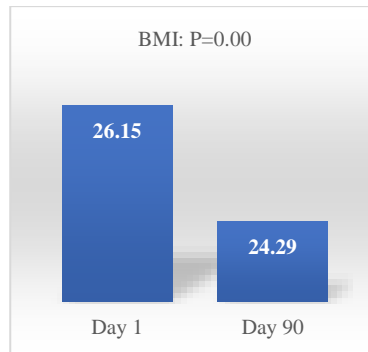


Table 6: Mean, median and standard deviation in VO₂Max

n=25	Day 1	Day 90	Day 1	Day 90
	Mean + Std		Median	
VO ₂ max	12.57±5.73	24.94±5.19	11.2	25

Table 7: Statistical analysis of change in VO₂Max in patients

ANOVA: Single Factor					
SUMMARY					

Groups	Count	Sum	Average	Variance		
VO₂max Day 1	25	314.34	12.57	34.17		
VO₂max Day 90	25	623.55	24.94	28.04		
ANOVA						
Source of Variation	SS	df	MS	F	P-value	F crit
Between Groups	1912.22	1	1912.22	61.48	0.00	4.04
Within Groups	1493.00	48	31.10			
Total	3405.21	49				

Table 8: Mean, median and standard deviation in Duke's trade mill score.

n=25	Day 1	Day 90	Day 1	Day 90
	Mean + Std		Median	
DTS	-12.56+3.74	-0.49+5.26	-13.1	1

Table 9: Statistical analysis of change in Duke's trade mill score in patients

ANOVA: Single Factor						
SUMMARY						
Groups	Count	Sum	Average	Variance		
DTS Day 1	25	-313.9	-12.56	14.55		
DTS Day 90	25	-12.2	-0.49	28.83		
ANOVA						
Source of Variation	SS	df	MS	F	P-value	F crit
Between Groups	1820.46	1	1820.46	83.93	0.00	4.04
Within Groups	1041.13	48	21.69			
Total	2861.59	49				

Discussion

The ischemic heart disease patients which were already on stable aggressive allopathy medications as well as basic lifestyle corrections for last consecutive three months and with stable health parameters when added on with Ischemia Reversal Program (IRP) therapy, further improved in respect to their ischemia status, Duke's trade mill score, VO₂Max, weight and BMI. The observed improvements in clinical parameters can be attributed to the multifaceted approach of IRP therapy.

1. Centripetal oleation medicated oil massage termed as Snehana in Ayurveda and Thermal vasodilation steam bath termed as Swedana in Ayurveda improves vascular elasticity, relieves circulatory congestion, dilates blood vessels, reduces ischemia, lowers high BP and reduces preload and afterload on the heart.
2. Reverse Diet therapy: Is a high ORAC value high antioxidant diet. It scavenges free radicals responsible for oxidative damage to the endothelium of blood vessels and thereby improves health of coronary arteries and reduces inflammation and plaque formation. It improves

HDL cholesterol levels, reduces LDL cholesterol, empowers reverse cholesterol transport mechanism and helps to reduce coronary atherosclerosis⁶. It also reduces weight and thereby reduces cardiac work-load. It also helps normalize other risk factors like high blood pressure, central obesity and diabetes.

3. Ayurvedic herbal medicines: Tribulus terrestris⁷ improves Nitrous Oxide mediate coronary vasodilation, thereby improves coronary perfusion and reduces ischemia and angina. Curcuma longa, Emblica officinalis⁸, and Ricinus communis reduces inflammation of the endothelium, thereby improving endothelial function, elasticity and compliance. It also helps balance HDL to LDL ratio, empowers reverse cholesterol transport mechanism and thereby helps regression of coronary atheromatous plaque. Terminalia arjuna⁹ is cardioprotective and cardiotoxic. It improves cardiac endurance, contractile power of cardiac muscles and protects cardiac myocytes from damage.
4. Walking Exercise: improves cardiac as well as peripheral circulation, improves vascular health, improves cardiac endurance, helps regress the coronary plaque.

Conclusion

The findings suggest that IRP therapy, as an adjunct to the conventional medical treatment, significantly improves ischemic status, Duke's trade mill score, VO₂max, and BMI in IHD patients. This integrative approach holds promise for enhancing the quality of life and reducing dependency on conventional medications in IHD patient population. Further prospective research on larger population is warranted to validate these findings and elucidate the underlying mechanisms of action.

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