Original Research Article

The Role of Ischemia Reversal Program in Improving Quality of Life by Reducing Myocardial Ischemia and Risk of Heart Disease

ABSTRACT

Background: Curbing the prevalence rates of ischemia heart disease presents a formidable challenge owing to a complex interplay of determinants such as low diagnostic rates, poor patient medication adherence, and less practice of evidence-based interventions. Ischemia Reversal Program (IRP) is an alternative therapy for ischemic heart disease patients, it is a combination of *Panchakarma* and allied therapy. The study intended to assess the role of IRP in improving quality of life by reducing myocardial ischemia and risk of heart disease.

Methods: A prospective, observational, single-centre study was conducted at Madhavbaug Cardiac Care Clinic from March 2021 to December 2022. Patients aged 18 years and above diagnosed with ischemic heart disease and that had participated in the IRP for a minimum of 7 sessions over a 90-day duration were included in this study. Data at baseline was compared with data at the 90-day follow-up.

Results: Of the 35 patients screened, 23 patients were included in the present study. Mean age of the study patients was 55.30 ± 8.01 years and 78.3% were male. The VO_2 max significantly improved from 17.53 ± 9.17 on day 1 to 26.93 ± 7.71 at day 90. Similarly, the Duke treadmill score significantly improved from 5.08 ± 3.68 on day 1 to 8.30 ± 3.13 on day 90.

Conclusion: The IRP can be an effective treatment to reduce risk of mortality due to heart disease and to improve quality of life in stable ischemic heart disease patients.

Keywords: Ayurveda**,** coronary artery disease**,** ischemic heart disease, *Panchakarma,* VO_2 max

1.0 INTRODUCTION

Ischemic heart disease is one of the foremost causes of morbidity and mortality in adults in India. This disease is accountable for 1.5 million deaths with a mortality rate of 109.23 deaths per 100,000 population in 2019. This also contributed to 7.79% of the total disability-adjusted life years (DALYs). This disease greatly affects the working population, thereby impacting the economic status of the country (1).

Pharmacotherapy remains the cornerstone treatment for ischemic heart disease patients. Drugs belonging to classes of angiotensin converting enzyme (ACE) inhibitors, calcium channel blockers (CCB), and beta-blockers (BB) have been implemented in the treatment strategy of these ischemic heart disease patients as well as ischemic heart disease patients with hypertension as an underlying comorbidity (2). However, low diagnostic rates, poor patient medication adherence, and less practice of evidence-based interventions spur an increase in healthcare expenditure (3). The World Health Organization has estimated 237 million US dollars direct health care expenditure to be incurred by India due to indirect loss of productivity due to ischemic heart disease (4). Hence, the need to explore alternative therapeutic interventions for ischemic heart disease.

The Ayurvedic practice of medicine, a traditional healing practice originating in India accentuates the use of herbs, minerals, and medicinal plants to address various health conditions, including those in acute phase of disease. The medications are often prepared

based on the patient-specific needs and doshas as per Ayurveda principles (5). *Panchakarma* along with adjunct allopathic medication is used by Ayurvedic physicians. The IRP is a combination of *Panchakarma* and allied therapy. Against this background, this study intended to assess the role of IRP in improving quality of life by reducing myocardial ischemia and risk of heart disease.

2.0 MATERIALS & METHODS

2.1 Study design & patient population

A prospective, observational, single-centre study was conducted at Madhavbaug Cardiac Care Clinic from March 2021 to December 2022. Patients aged 18 years and above, regardless of gender diagnosed with ischemic heart disease who had participated in the Ischemia Reversal Program (IRP) for a minimum of 7 sessions over a 90-day duration were included in this study. The study conformed to the principles of Good Clinical Practice (6) and the Declaration of Helsinki (7). Patients were enrolled after written informed consent was obtained.

2.2 Ischemia Reversal Program

The IRP is a 3-step procedure which was initiated after patients consumed a light breakfast. One session lasted 60–75 mins. The first procedure was *Snehana* which was external oleation through centripetal upper strokes directed towards the heart. The herbs used were 100 ml of 80% sesame oil and 20% lavender oil. The duration of this procedure was 30–35 mins. The second procedure was *Swedana* which was passive heat therapy using Dashmoola i.e. a group of 10 herbal roots with steam at less than 40° C. The duration of this procedure was 10–15 mins with 3–4 mins of relaxation after the procedure. The third

procedure was *Basti* which was per rectal drug administration using a rectal solution. 100 ml luke-warm decoction of Gokshura (*Tribulus terrestris*), Haridra (*Curcuma longa*), and Amalaki (*Emblica officinalis*) was used. The duration of this procedure was 15 mins. The patients adhered to 1200 calories/day intake.

2.3 Cardiac stress test and Duke treadmill score

Cardiac stress testing was done following the Modified Bruce Protocol. Their maximum work load was assessed in terms of metabolic equivalents (METs) and this was multiplied by 3.5 to give VO_2 max. Duke treadmill score ≥5 indicates low risk for cardiovascular events. It implies that this patient subgroup does not need further investigation with coronary angiography. A score ≤-11 indicates a high risk for cardiovascular events. These patients require further investigation with coronary angiography. A score between 4 and -10 indicates intermediate risk. Such patients may require further investigation with myocardial perfusion scanning or coronary angiography, or both, depending on the protest probability.

2.4 Data collection

On day 1 of the IRP program, a detailed patient history was documented. Anthropometric measurements, VO_2 max, and Duke treadmill score were also recorded as per international standards (8). These details were again recorded on day 90 of the IRP program. Data of day 1 was compared with data of day 90. Data of only those patients who had complete data for 90 days was included in this analysis.

2.5 Statistical analysis

Categorical data are expressed as number (percentage) and continuous data are expressed as mean ± standard deviation. Paired t-test was used to determine the difference between baseline and the 90-day follow-up. R version 3.4.2 software was used to analyse the data.

3.0 RESULTS

3.1 Demographics, anthropometric measurements and laboratory investigations

A total of 35 patients were screened, however only 23 patients competed the stress test and hence were included in the study. Mean age of the study patients was 55.30 ± 8.01 years. Of the 23 patients, 18 (78.3%) were male. Weight decreased from 67.53 ± 11.11 kg to 62.95 ± 8.36 kg ($p<0.001$). Body mass index decreased from 26.42 ± 4.21 to 24.60 ± 3.18 ($p<0.001$). Abdomen girth decreased from 99.50 ± 10.90 cm to 94.00 ± 8.24 cm (<0.001). Systolic and diastolic blood pressure decreased from 132.26 ± 17.71 mmHg to 118.78 ± 9.68 ($p<0.001$) and 84.61 ± 11.34 mmHg to 78.00 ± 7.20 mmHg ($p<0.001$), respectively. VO_2 max increased from 17.53 ± 9.17 to 26.93 ± 7.71 ($p<0.001$). MET value increased from 4.91 ± 2.64 to 7.73 ± 2.12 ($p<0.001$). Duke treadmill score increased from 5.08 ± 3.68 to 8.30 ± 3.13 ($p<0.001$). The details of the demographics, anthropometric measurements and laboratory investigations of the study patients at baseline and follow-up is detailed in **Figure 1**.

3.2 Impact of Ischemia Reversal Program on weight

Weight decreased for the 56–90 years age group (day 1: 67.31 ± 13.03 kg and day 90: 61.67 ± 10.00 kg, percent change: -8.37%), males (day 1: 69.38 ± 8.74 kg and day 90: 64.46 ± 6.04 kg, percent change: -7.10%), low-risk patients according to VO_2 max (day 1: 70.71 ±

10.93 kg and day 90: 64.81 ± 6.57 kg, percent change: -5.90%), and also low-risk patients according to Duke treadmill score classification (day 1: 72.15 ± 9.84 kg and day 90: 65.76 ± 6.32 kg, percent change: -8.85%). The impact of the IRP on weight of study patients is demonstrated in **Table 1.**

3.3 Impact of Ischemia Reversal Program on body mass index

Body mass index decreased for the 56–90 years age group (day 1: 26.69 ± 4.84 and day 90: 24.36 ± 3.39, percent change: -8.76%), males (day 1: 26.01 ± 3.07 and day 90: 24.15 ± 2.21, percent change: -7.17%), low-risk patients according to VO_2 max (day 1: 26.65 ± 3.61 and day 90: 24.47 ± 1.86, percent change: -8.19%), and also low-risk patients according to Duke treadmill score classification (day 1: 28.24 ± 4.81 and day 90: 25.74 ± 3.46, percent change: -8.86%). The impact of the IRP on body mass index of study patients is demonstrated in **Table 2.**

3.4 Impact of Ischemia Reversal Program on abdomen girth

Abdomen girth decreased for the 56–90 years age group (day 1: 101.18 ± 13.35 cm and day 90: 94.45 ± 9.27 cm, percent change: -6.65%), males (day 1: 98.75 ± 7.67 cm and day 90: 93.17 ± 6.34, percent change: -5.65%), low-risk patients according to VO_2 max (day 1: 99.75 ± 9.39 and day 90: 93.63 ± 6.08, percent change: -6.14%), and also low-risk patients according to Duke treadmill score decreased (day 1: 103.64 ± 12.77 cm and day 90: 96.55 ± 9.13 cm, percent change: -6.84%). The impact of the IRP on abdomen girth of study patients is demonstrated in **Table 3.**

3.5 Impact of Ischemia Reversal Program on VO_2 max

VO_2 max increased for the 56–90 years age group (day 1: 16.89 ± 9.86 and day 90: 27.17 ± 8.37, percent change: 60.90%), males (day 1: 18.23 ± 9.92 and day 90: 28.86 ± 6.97,

percent change: 58.25%), low-risk patients according to VO_2 max (day 1: 28.54 ± 6.18 and day 90: 33.82 ± 4.53, percent change: 18.52%), and also intermediate-risk patients according to Duke treadmill score (day 1: 11.12 ± 3.19 and day 90: 22.43 ± 5.56, percent change: 101.66%). The impact of the IRP on VO_2 max of study patients is demonstrated in **Table 4.**

3.6 Impact of Ischemia Reversal Program on Duke treadmill score

Duke treadmill score increased for the 56–90 years age group (day 1: 4.33 ± 3.87 and day 90: 7.58 ± 3.09, percent change: 75.21%), males (day 1: 5.24 ± 3.60 and day 90: 8.83 ± 2.62, percent change: 68.61%), severe-risk patients according to VO_2 max (day 1: 1.78 ± 2.22 and day 90: 6.23 ± 3.62, percent change: 250.70%), and also intermediate-risk patients according to Duke treadmill score (day 1: 2.05 ± 2.06 and day 90: 6.54 ± 3.08, percent change: 219.11%). The impact of the IRP on the Duke treadmill score of study patients is demonstrated in **Table 5.**

4.0 DISCUSSION

Ischemic heart disease prevalence has increased significantly throughout the years such that it has become epidemic. The IRP has been designed to improve blood flow to the heart and increase tolerance levels to improve quality of life. It is associated with significant improvements in Duke treadmill score and VO_2 max leading to better prognosis in ischemic heart disease patients (2). A study published in 2018 (9) sought to investigate the efficacy of IRP on VO_2 max and Duke treadmill score an adjunctive therapy to standard anti-ischemic therapy in patients with ischemic heart disease patients. Study findings revealed VO_2 max significantly increased from 20.29 ± 6.72 to 29.40 ± 6.7. Duke treadmill score was also assessed. At baseline 50% patients were at moderate risk and 31.6% were at high risk which significantly improved to 47.4% moderate risk and 52.6% at low risk. Dependency on

adjunctive medication also deterred. These findings are in line with findings of the current study

Hypertension is one of the predominant risk factors of ischemic heart disease. According to the World Health organization, hypertension is accountable for 16% ischemic heart disease related deaths (2) with cardiovascular risk mortality increasing from blood pressure as low as 110/70 mmHg (10). Thus, maintaining blood pressure values within normal ranges remains the cornerstone of both primary and secondary ischemic heart disease prevention. Maintaining blood pressure of 140/90 mmHg is recommended for primary prevention, while values of 130/85 mmHg is recommended for secondary prevention (10). A study published in 2018 (2) sought to evaluate the VO_2 max and Duke treadmill score on IRP on ischemic heart patients with hypertension. It also sought to assess the effect of IRP on blood pressure. VO_2 max significantly increased from 20.74 ± 7.25 to 29.69 ± 6.62. Moreover, there was a decrease in the number of moderate and high-risk patients at the 90-day follow-up. Systolic and diastolic blood pressure significantly decreased from 127.68 ± 13.65 mmHg to 122.74 ± 11.65 mmHg and from 78.95 ± 7.37 mmHg to 75.78 ± 6.92 mmHg, respectively. Moreover, a recently published study with a similar aim (4) observed significant improvement in Duke treadmill score from -1.76 to 6.34.

Over the past two decades, obesity has emerged as a global public health concern affecting both children and adults. Several studies have revealed obesity as an independent risk factor for cardiovascular disease (12). Moreover, several large prospective studies assessed the association between obesity and coronary heart disease and revealed a 40% increase in mortality for every 5 kg/m^2 increased in body mass index above 25 kg/m^2 (13). Adipokines released by adipose tissue can induce endothelial dysfunction, systemic inflammation, and insulin resistance – all these contributes towards the risk of atherosclerosis (14-16). The IRP has also been assessed in the subgroup of obese patients. The study (9)

sought to understand the role of low carbohydrate diet and Ayurveda based IRP in management of ischemic heart disease with obesity. Obese patients were defined as those with body mass index ≥30 kg/m^2. The VO_2 max increased significantly from 17.82 ± 7.23 on day 1 to 26.65 ± 6.14 at day 90.

The Ischemia Reversal Program (IRP) is a combination of *Panchakarma* and allied therapy. This therapy has been assessed in ischemic heart disease patients including those with underlying comorbidities such as hypertension and obesity.

Study limitations

The study has a few limitations that deserve mention. Firstly, the small sample size due to which the study findings cannot be generalized. Secondly, this was a single arm study, a comparator arm of standard therapy might have provided further insights. Thirdly, a longer follow-up duration might have provided insights into the long-term outcomes of the IRP.

5.0 CONCLUSION

The Ischemia Reversal program can be effective treatment to reduce risk of mortality due to heart disease and to improve quality of life in stable ischemic heart disease patients.

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TABLES

Table 1: Impact of Ischemia Reversal Program on weight

Variable	Weight (kg) Day 1 n=23	Weight (kg) Day 90 n=23	Change (%)
Age, years			
25–55	67.73 ± 9.01	64.13 ± 6.28	-5.32
56–90	67.31 ± 13.03	61.67 ± 10.00	-8.37
Gender			
Male	69.38 ± 8.74	64.46 ± 6.04	-7.10
Female	60.84 ± 15.37	57.54 ± 12.36	-5.42
VO_2 max			
Low-risk	70.71 ± 10.93	64.81 ± 6.57	-5.90
Intermediate-risk	70.19 ± 10.17	65.99 ± 6.03	-4.20
Severe-risk	62.01 ± 9.92	58.44 ± 9.71	-3.58
Duke treadmill score classification			
Low-risk	72.15 ± 9.84	65.76 ± 6.32	-8.85
Intermediate-risk	63.29 ± 10.51	60.38 ± 9.14	-4.61

All data are expressed as mean ± standard deviation.

Table 2: Impact of Ischemia Reversal Program on body mass index

Variable	Body mass index Day 1 n=23	Body mass index Day 90 n=23	Change (%)
Age, years			
25–55	26.18 ± 3.52	24.28 ± 2.95	-5.19
56–90	26.69 ± 4.84	24.36 ± 3.39	-8.76
Gender			
Male	26.01 ± 3.07	24.15 ± 2.21	-7.17
Female	27.91 ± 6.69	26.2 2 ± 5.05	-6.06
VO_2 max			
Low-risk	26.65 ± 3.61	24.47 ± 1.86	-8.19
Intermediate-risk	28.42 ± 5.22	26.65 ± 3.70	-6.23
Severe-risk	24.45 ± 2.58	22.94 ± 2.68	-6.21
Duke treadmill score classification			
Low-risk	28.24 ± 4.81	25.74 ± 3.46	-8.86
Intermediate-risk	24.76 ± 2.63	23.55 ± 2.47	-4.87

All data are expressed as number (percentage) or mean ± standard deviation.

Table 3: Impact of Ischemia Reversal Program on abdomen girth

Variable	Abdomen girth Day 1 n=23	Abdomen girth Day 90 n=23	Change (%)
Age, years			
25–55	97.96 ± 7.70	93.58 ± 7.15	-4.47
56–90	101.18 ± 13.35	94.45 ± 9.27	-6.65
Gender			
Male	98.75 ± 7.67	93.17 ± 6.34	-5.65
Female	102.2 ± 18.03	97.0 ± 12.51	-5.09
VO_2 max			
Low-risk	99.75 ± 9.39	93.63 ± 6.08	-6.14
Intermediate-risk	102.57 ± 14.39	96.29 ± 10.55	-6.13
Severe-risk	96.56 ± 7.44	92.38 ± 7.31	-4.34
Duke treadmill score classification			
Low-risk	103.64 ± 12.77	96.55 ± 9.13	-6.84
Intermediate-risk	95.71 ± 6.93	91.67 ± 6.51	-4.22

All data are expressed as number (percentage) or mean ± standard deviation.

Table 4: Impact of Ischemia Reversal Program on VO_2 max

Variable	VO_2 max Day 1 n=23	VO_2 max Day 90 n=23	Change (%)
Age, years			
25–55	18.11 ± 8.45	26.72 ± 7.05	47.53
56–90	16.89 ± 9.86	27.17 ± 8.37	60.90
Gender			
Male	18.23 ± 9.92	28.86 ± 6.97	58.25
Female	14.97 ± 4.92	20.02 ± 6.12	33.72
VO_2 max			
Low-risk	28.54 ± 6.18	33.82 ± 4.53	18.52
Intermediate-risk	14.45 ± 1.69	26.45 ± 6.22	12.00
Severe-risk	9.21 ± 1.60	20.48 ± 5.23	11.27
Duke treadmill score classification			
Low-risk	24.51 ± 8.45	31.85 ± 6.66	29.95
Intermediate-risk	11.12 ± 3.19	22.43 ± 5.56	101.66

All data are expressed as mean ± standard deviation.

Table 5: Impact of Ischemia Reversal Program on Duke treadmill score

Variable	Duke treadmill score Day 1 n=23	Duke treadmill score Day 90 n=23	Change (%)
Age, years			
25–55	5.78 ± 3.35	8.96 ± 3.02	55.12
56–90	4.33 ± 3.87	7.58 ± 3.09	75.21
Gender			
Male	5.24 ± 3.60	8.83 ± 2.62	68.61
Female	4.52 ± 3.91	6.38 ± 3.97	41.15
VO_2 max			
Low-risk	8.46 ± 1.79	10.29 ± 1.93	21.57
Intermediate-risk	5.00 ± 3.11	8.40 ± 1.88	68.00
Severe-risk	1.78 ± 2.22	6.23 ± 3.62	250.70
Duke treadmill score classification			
Low-risk	8.39 ± 1.65	10.22 ± 1.77	21.78
Intermediate-risk	2.05 ± 2.06	6.54 ± 3.08	219.11

All data are expressed as number (percentage) or mean ± standard deviation.

Figure 1: Demographics, anthropometric measurements and laboratory investigations at baseline and follow-up