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ROLE OF NON INVASIVE AYURVEDA BASED DETOXIFICATION ON QUALITY OF LIFE AND MYOCARDIAL ISCHEMIA ASSESSED BY CARDIAC STRESS TESTING

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ABSTRACT

Background: Ischemic heart disease (IHD) have reached epidemic levels on global scale. Nearly 18 million deaths have been reported globally due to cardiovascular diseases. Ischemia Reversal Program (IRP) is a form of Ayurvedic therapy which combines use of panchkarma and allied therapy in the management of IHD. **Aim and objectives:** The present study was planned to study the effectiveness of IRP therapy in patients of myocardial ischemia attending Madhavbaug clinics in Pune, Maharashtra. **Materials and methods:** This was a retrospective study conducted from May 2019 to October 2019, wherein we identified the data of patients suffering from IHD (positive for inducible ischemia from stress test) of either gender or any age, and who had attended the out-patient departments (OPDs) at Pune, Maharashtra, India. The data of patients who had been administered IRP with minimum 7 sittings over a span of 12 weeks were considered for the study. **Results:** In the present study, medical records of 75 patients of IHD were analyzed. At the end of IRP therapy there was statistically significant reduction in weight as compared (64.10±10.54 kg) to baseline (69.52±12.18 kg) with a p-value of 0.01. Similar trend was observed in BMI, SBP, and DBP. VO2 peak was improved at the end of therapy i.e. 26.39±5.55 mL/kg/min as compared to baseline i.e. 15.72±5.03 mL/kg/min ($p<0.001$). DTS improved from -2.99±5.81 at baseline to 3.29±6.33 at week 12 of IRP therapy ($p<0.0001$). Conclusion: Findings of present study suggest that the application of the IRP can delay the onset of ischemia and result in an improvement in the overall quality of life.

KEYWORDS: Ischemic Heart Disease, Ischemia Reversal Program, Ayurveda, Panchkarma, VO2 peak, Dukes Treadmill score.

INTRODUCTION

Ischemic heart disease (IHD) have reached epidemic levels on global scale. Nearly 18 million deaths have been reported globally due to cardiovascular diseases. Most importantly, almost 60-70% of these deaths are being reported from developing countries. The prevalence of cardiovascular diseases are reducing gradually in developed countries, but at the same time it is increasing progressively in developing countries like India. This is particularly more pronounced in urban population as compared to rural population. Reasons cited for such finding are industrialization, increased sedentary lifestyle, rise of lifestyle related diseases. Sedentary lifestyle is considered to be one of the major culprit for rise in cardiovascular disease in urban population, as India is witnessing rise in related diseases like obesity, diabetes mellitus (DM), hypertension (HTN), dyslipidemia, etc. These in turn leads to increased morbidity and mortality and ultimately burden on healthcare system is increased.[1] According to Global Burden of Disease study the doubling time of morbidity and mortality rate due to CVD in India has been estimated to be 30 years.[2]

These lifestyle diseases are chronic in periodicity. On persistence, these lead to imbalance of demand and supply of oxygen to tissues, particular myocardium. Still further these hemodynamic alterations ultimately lead to damage to vascular endothelium.[3]

Due to its multifactorial nature, management of IHD is not always straightforward. Treatment strategies have to be tailored after giving due considerations to age,

comorbidities, co-administered drugs, etc. Despite availability of armamentarium of conventional medicines and extensive guidelines the morbidity and mortality rates of IHD are rising in India. Thus, it is the need of the hour to explore novel therapeutic alternative that will be effective in not only controlling the disease but also help to attenuate anxiety, fear, cost of therapy associated with IHD.[4] Major aim of therapy in IHD is to restore the balance between demand and supply of oxygen to tissues, optimization of blood pressure (BP), antiplatelet action, reduction in oxidative stress, etc.[4] It has been proven in various studies that a plethora of herbal drugs possess these actions, and therefore these drugs can serve as potential therapeutic option for management of IHD.[4]

Ayurveda is an ancient form of Medicine, which aims to cure the disease from its root cause. It recommends that acute phase of the disease should be managed by traditional herbal drugs and once the disease flare is controlled then maintenance phase is governed by administration of *Panchkarma. Panchkarma* is a multi-step procedure of internal cleansing the body from all the toxins.[5] Ischemia Reversal Program (IRP) is a form of Ayurvedic therapy which combines use of panchkarma and allied therapy in the management of IHD. Under this treatment regimen *Panchkarma* utilizes 3 main techniques, Snehana i.e. central oleation, Swedana i.e. passive heat therapy, and basti i.e. per rectal drug administration. All these techniques are well proven for their internal detoxification actions.[4]

It is well documented that IHD is associated with significant alteration in quality of life, depression, anxiety, etc.[6] Hence, the present retrospective study was planned to evaluate the effectiveness of IRP in patients of IHD. We evaluated the effect of IRP on maximum oxygen consumption/maximum aerobic capacity measured by VO2max (V-volume, O2-oxygen, max-maximum), Duke's treadmill score, Metabolic Equivalent if Task (MET), systolic (SBP) and diastolic BP (DBP), and dependency of these IHD patients on standard conventional medications.

MATERIALS AND METHODS

This was a retrospective study conducted from May 2019 to October 2019, wherein we identified the data of patients suffering from IHD (positive for inducible ischemia from stress test) of either gender or any age, and who had attended the out-patient departments (OPDs) at Pune, Maharashtra, India. The data of patients who had been administered IRP with minimum 7 sittings over a span of 12 weeks were considered for the study. Cases were identified, and data was assessed from the records of Madhavbaug clinics in Pune area, Maharashtra. The selection was based upon the availability of complete relevant baseline data (day 1 of IRP) and final day data (week 12 of IRP) of the patients.

The IRP is a 3-step procedure, which was performed on the patients of IHD after a light breakfast. One sitting of the procedure took 65-75 minutes, as described in table 1.[7,8]

Table 1: Study Treatment: Ischemia Reversal Program (IRP Kit)

Step of IRP	Type of Therapy	Herbs used for therapy	Duration of Therapy
Snehana	Massage or external oleation (centripetal upper strokes directed towards heart)	100 ml [Sesame oil (80%) + Lavender oil (20%)]	30-35 minutes
Swedana	Passive heat therapy	*Dashmoola* (group of ten herbal roots) with steam at ≤ 40 degrees Celsius)	10-15 minutes + 3 - 4 minutes of relaxation after procedure
Basti	Per rectal drug administration using a rectal solution.	Luke-warm *GHA* decoction *100 ml*	15 minutes

Where: GHA stands for Gokshura/Tribulus terrestris, Haridra/Curcuma longa, Amalaki/ Emblica officinalis.

Baseline recordings of Duke's treadmill score (DTS), VO2 peak, DBP, SBP, MET and other secondary parameters like body mass index (BMI) as per standard recommendations.[9] These parameters were again recorded at week 12 of IRP therapy. The dependency on standard medication was calculated both at baseline and week 12 of IRP as the percentage of patients out of the total enrolled ones who required a conventional allopathic therapeutic agent during the study period.

Duke's treadmill Score (DTS) is calculated by the formula[9]

Duke treadmill score = Maximum exercise time in minutes – (5×ST segment deviation in mm) – (4×angina index).

Where 0=no angina, 1=non-limiting angina, 2=exercise limiting angina.

The DTS is typically used for stratifying patients based on their risks and typically ranges from -25 to +15. Depending on the score, the patients were categorized into risk groups as shown in table 2.[9]

Table 2: Risk groups of patients of IHD according to Duke's treadmill score (DTS).

Risk Category	DTS criteria	Need for coronary angiography	4- year survival
Mild	≥5	No	99%
Moderate	+4 to -10	May require	-
Severe	≤10	Requires	79%

The maximum volume of oxygen that an individual can consume during intense, whole-body exercise is called as VO2max/ maximal aerobic capacity (ml/kg/min). A metabolic equivalent (MET) is defined as the amount of oxygen consumed by an individual at rest (also known as resting energy expenditure) ie, approximately 3.5 ml O2/kg/min.[10,11]

For the present study MET values were classified into three levels of exercise intensity: light exercise (<3.0 METS) an activity that results in only minimal perspiration and a very slight increase in breathing above normal; moderate exercise (3.0 to 6.0 METS an activity that results in definite perspiration and above normal breathing; and heavy exercise (>6.0 METS) an activity that results in heavy perspiration and heavy breathing.[11]

Statistical analysis: Data were pooled and coded in Microsoft Excel spreadsheet. R Version 3.4.1 software was used to analyse the data. Categorical data were represented in the frequency form and continuous data were presented as the Mean ± SD. McNemar-Bowker test was used to assess Duke treadmill score before and after week 12 of treatment. Paired t-test was used to assess the difference between baseline values and 12 weeks after treatment. Box plot and histogram were used to represent the graphs.

RESULTS

In the present study, medical records of 75 patients of IHD were analyzed. Mean age in the present study was 59.44 ± 13.12 years. Out of these, 41 were male (55%) and 34 were females (45%). Thus, male: female ratio was 1.2 (table 3).

Table 3: Baseline characteristics of the study subjects (n= 75).

Variable	N = 75
Age (years)	59.44 ± 13.12
Gender	
Male	41 (55%)
Female	34 (45%)

Data was expressed in % and mean ± SD

At the end of IRP therapy there was statistically significant reduction in weight as compared (64.10±10.54 kg) to baseline (69.52±12.18 kg) with a p-value of 0.01. Similar trend was observed in BMI, SBP, and DBP. VO2 peak was improved at the end of therapy i.e. 26.39±5.55 mL/kg/min as compared to baseline i.e. 15.72±5.03 mL/kg/min and the difference was highly statistically significant (p<0.001). DTS improved from -2.99±5.81 at baseline to 3.29±6.33 at week 12 of IRP therapy and the difference was highly statistically significant (p<0.0001) [table 4].

Table 4: Summary of mean change observed from baseline after 12 weeks for different parameters.

Parameter	Baseline	After 12 weeks	p-value
Weight	69.52±12.18 kg	64.10±10.54 kg	0.01
Body Mass Index	26.78±6.24 kg/m^2	23.83±5.37 kg/m^2	0.04
Systolic Blood Pressure	133.58±19.44 mmHg	122.1±17.84 mmHg	0.01
Diastolic Blood Pressure	80.27±12.02 mmHg	71.03±11.38 mmHg	0.01
VO2 peak	15.72±5.03 mL/kg/min	26.39±5.55 mL/kg/min	<0.001
Duke Treadmill Score (DTS)	-2.99±5.81	3.29±6.33	<0.0001

On analyzing the angina index, it was found that mean angina index was 1.53 at baseline and it reduced to 0.44 at week 12 of IRP (p<0.001) [figure 1].

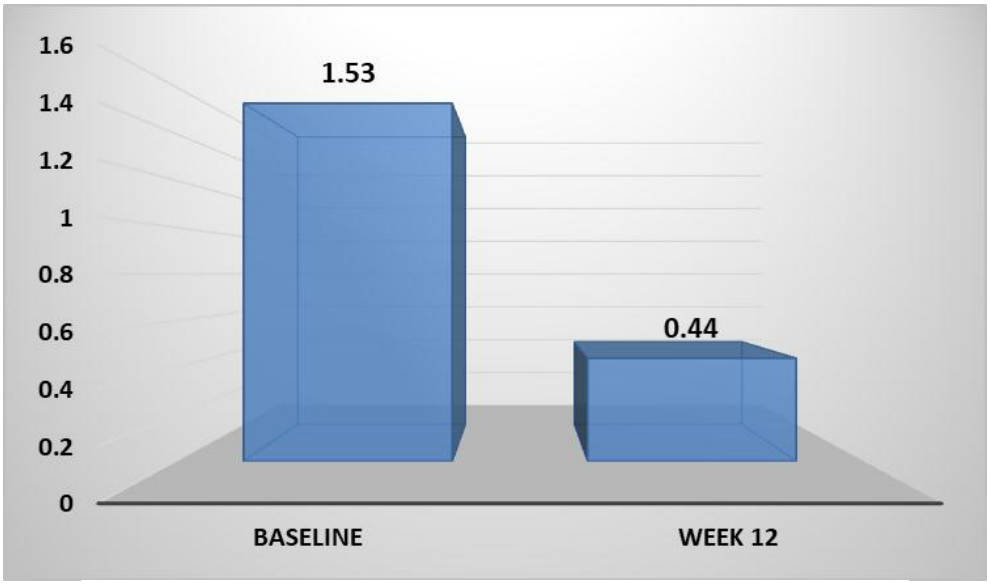

Figure 1: Mean Angina index in patients of the IHD in the present study.

On analyzing the DTS, number of patients in low risk category increased from 13 (29%) at baseline to 27 patients (63%) at 12 weeks of IRP therapy. Similarly, there was reduction in number of patients in moderate to severe risk categories after 12 weeks of IRP therapy. Overall there was shift of patients from severe risk to low risk group. The difference was highly statistically significant (p<0.001) [table 5].

Table 5: Duke's trade mill score in patients of IHD in the present study.

Timeline	Duke's treadmill score (DTS) [n=44]			
	Low risk (≥5)	Moderate risk (-10 to 4)	Severe risk (≤ -11)	p-value
Baseline	13 (29%)	25 (58%)	6 (13%)	<0.001
Week 12	27 (63%)	14 (32%)	3 (5%)	

Ability to perform strenuous activity was evaluated on the basis of MET usage. At baseline 13 (29%), 25 (58%), and 6 patients (12%) were able to perform light, moderate and vigorous exercise, respectively. After 12 weeks of IRP therapy 2 (2%), 13 (29%), and 29 patients (69%) were able to perform vigorous exercise, respectively. Thus, there was increase in number of patients who were able to perform rigorous activities after IRP therapy as compared to baseline and the difference was highly statistically significant (p<0.001) [table 6].

Table 6: Table indicating shift in the Metabolic Equivalent of Task over time.

Timeline	Metabolic equivalent of task (MET) [n=44]			
	Light exercise (< 3.0 METS)	Moderate exercise (3 to 6 METS)	Vigorous exercise (> 6 METS)	p-value
Baseline	13 (29%)	25 (58%)	6 (12%)	<0.001
Week 12	2 (2%)	13 (29%)	29 (69%)	

On analyzing the dependency on conventional drugs, it was found that overall the consumption of all drug categories was reduced after IRTP therapy. 3 (4%) patients were not taking medications at baseline which increased to 17 patients (23%) after 12 weeks of IRP therapy (table 7).

Table 7: Consumption of Allopathic medication at baseline and post 12 weeks.

Medication	Baseline	After 12 weeks
Angiotensin II receptor blockers	12	7
β-blocker	7	4
Diuretics	4	2
Ca^{2+} channel blockers	6	4
NSAIDs	11	4
Biguanides	39	25
DPP4	12	7
Sulfonylureas	19	9
Insulin	20	11
Antiplatelets	11	6
Statins	18	10
Nitrates	8	4
No medication	3	17

DISCUSSION

IHD is a major cause of illness and death worldwide, although there are many similar treatments available. Therefore, it is an admirable need for the present to look at the novel treatment option for the management of IHD. Common drugs used for the treatment of IHD action by correcting the difference between oxygen demand and cardiac output, hypolipidemic action, antioxidant effect, lowering BP. Ayurveda may serve as a promising treatment for IHD, since many herbal remedies have been found to have similar therapeutic effects to conventional medicine. Ayurvedic physicians offer panchkarma therapy in the management of IHD. The 3 step panchkarma in the Swedana, Snehana and Basti method is given to IHD patients, as part of the IRP.

IRP can act by reducing sensitivity activation (reducing BP) by Snehana's anxiolytic action, reducing myocardial oxygen demand by reducing sodium and water load (pre-cardiac load) by Swedana and Basti helps release nitric oxide from vascular endothelium, is a coronary vasodilator, anti-inflammatory and antioxidant action using a decoction made by Gokshura i.e. Tribulus terrestris, Haridra i.e. Curcuma longa, and Amalaki i.e. Emblica officnalis. They also help to improve the circulation of the heart.[13,14,15,16] For the purpose of

examining the effect of IRP on IHD on HTN, there has been a marked improvement in VO2max, Duke's printing school, SBP and a significant statistical improvement in DBP by the end of 90 of the complete process. Since DBP and SBP are one of the predictors of IHD, significant reductions in both in our current study show good predicts because lowering SBP and DBP reduces ventricles loading, thus reducing cardiac oxygen demand.[17]

The maximum amount of oxygen consumption in strenuous physical activity is measured by VO2max. It decreases in IHD patients due to diastolic dysfunction, which brings to the clinic as a decrease in activity volume.[18] Because of its role in risk identification, in addition to diagnostic and predictive tools, Duke's treadmill points are very important for IHD and HTN patients. Scores <-11 indicate a high-risk group, requiring coronary angiography with a 4-year survival rate of less than 80%. A range of 10 to 4 indicates a moderate risk group, which requires a myocardial perfusion scan or coronary angiography, depending on the patient's general condition. Points of > +5 indicate a low-risk group, which does not require any incoming investigation to be considered and its 4 year survival rate is 100%.[18]

In our VO2max study, Duke, SBP and DBP scores were significantly improved to standard levels. Studies have shown that the development of these disorders is associated with better prognosis in IHD patients with a history of HTN.[18,19] Therefore, the findings of our present study suggest that the reduction of these parameters should be associated with a reduction in heart disease and death. However, some such studies should be performed on a national scale, perhaps with a larger sample size, 2 treatment arms to make direct comparisons with standard treatment, more follow-up time, so that the findings in our study can be generalized.

CONCLUSION

As significant improvements in the primary endpoints such as Duke treadmill score (DTS) and metabolic equivalent (MET) and secondary endpoints such as maximal oxygen uptake capacity (VO_2 max), body mass index (BMI), systolic blood pressure (SBP), and weight were observed, these results suggest that the application of the IRP can delay the onset of ischemia and result in an improvement in the overall quality of life.

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