ORIGINAL RESEARCH PAPER

Ayurveda

IMPACT OF AYURVEDA BASED DETOXIFICATION ON PREDICTED RISK OF MORTALITY IN KNOWN IHD PATIENTS.

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

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ABSTRACT

Background: Heart problems are considered a global epidemic, with cardiovascular disease being spread all over the world. Ischemia Reversal Program (IRP) is a form of Ayurvedic therapy which combines use of panchkarma and allied therapy in the management of ischemic heart disease (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 western 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 West 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 50 patientsl of IHD were analyzed. At the end of IRP therapy there was statistically significant reduction in weight, body mass index, Systolic and Diastolic blood pressure. VO2 peak was improved at the end of therapy i.e. 26.26±6.47 mL/kg/min as compared to baseline i.e. 15.21±5.99 mL/kg/min and the difference was highly statistically significant ($p<0.001$). DTS improved from -3.56±7.89 at baseline to 3.22±8.18 at week 12 of IRP therapy and the difference was highly statistically significant ($p<0.0001$). **Conclusion:** Findings of present study suggest that IRP can serve as effective therapeutic option for the management of ischemic heart disease.

INTRODUCTION:

The coronary heart disease (CVD) is a global phenomenon that has shown an increase in the incidence of both developed and developing countries.[1] According to the estimated Registrar General of India, CVD contributed to 17% of deaths and 26% of adult deaths in 2001-2003, which increased to 23% of the total and 32% of adult deaths 2010-2013. The World Health Organization (WHO) and the Global Burden of Disease Study have also highlighted the growing trends in years of life lost (YLLs) and years of disability living (DALY) from CVD in India.[2] IHD contributes significantly to deaths due to CVD in India (> 80%).[3]

The current IHD management protocol includes long-term treatment with drugs such as antiplatelet agents (Aspirin / Clopidogrel), beta blockers, ACE inhibitors that reduce cardiovascular function, corrective dyslipidemia statements.[4] However, long-term use of these drugs may inevitably work with serious safety concerns.[4]Therefore, the search for safe and effective alternatives is very important in the management of IHD.

Ayurveda is a traditional medicine system of traditional science in India. Ayurveda means 'knowledge of life', consisting of two Sanskrit words, Ayu (Life) and Veda (Knowledge or Science). The main goal of Ayurveda is to achieve a balance between body structures and structures, which ultimately lead to good health. Any imbalance or inequality due to external or internal factors can lead to the development of diseases.[5] Ayurvedic therapy aims to restore balance through a variety of techniques, types, diets and medications.[6]

At our center (Madhavbaug Clinics and Hospital) Ayurvedic doctors use a policy to treat IHD with a combination of herbal remedies such as Snehana, Sweden, Basti kadha i.e. Ischemia Reversal Program (IRP) is a form of Ayurvedic therapy which combines use of panchkarma and allied therapy in the management of IHD.[7]

It is well documented that IHD is associated with significant alteration in quality of life, depression, anxiety, etc.[8] 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.

However, a literature search revealed that there was a shortage of published literature to demonstrate the effectiveness of this treatment of IHD patients in western Maharashtra. At this domain, a current study was conducted to demonstrate the effectiveness of IRP in the treatment of IHD.

SUBJECTS 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 western 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 Western 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.[9,10]

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 (antihypertensive action, antispasmodic, hypolipidemic, cardioprotective actions); Haridra/Curcuma longa (hypotensive, anticoagulant, antioxidant); Amalaki/ Emblica officinalis (cardioprotective, hypolipidemic, antioxidant).11-14

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 [sane-25]. 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:15

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 2.15

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.[16]

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.[17]

Statistical analysis:

Data were pooled and coded in Microsoft Excel spreadsheet. R Version 3.4.1 software was used to analyze 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. Patient record data selection for the present study is depicted in figure

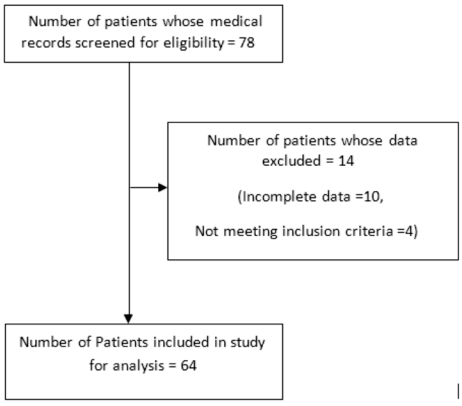


Figure 1: Patient record selection for the present study.

Results:

In the present study, medical records of 64 patients of IHD were analyzed. Mean age in the present study was 59.16 ± 9.81 years. Out of these, 35 were male (55%) and 29 were females (45%). Thus, male: female ratio was 1.2 (table 3).

Table 3: Baseline characteristics of the study subjects (n= 64)

Variable	N = 64
Age (years)	59.16 ± 9.81
Gender	
Male	35 (55%)
Female	29 (45%)

Data were expressed in % and mean ± SD

At the end of IRP therapy there was statistically significant reduction in weight as compared (64.51±11.44 kg) to baseline (67.32±10.93 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. 26.26±6.47 mL/kg/min as compared to baseline i.e. 15.21±5.99 mL/kg/min and the difference was highly statistically significant (p<0.001). DTS improved from -3.56±7.89 at baseline to 3.22±8.18 at week 12 of IRP therapy and the difference was highly statistically significant (p<0.0001) [table 4].

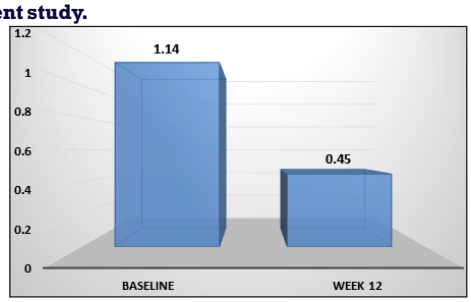
Table 4: Summary of mean change observed from baseline after 12 weeks for different parameters

Parameter	Baseline	After 12 weeks	p-value
Weight	67.32±10.93 kg	64.51±11.44 kg	0.01
Body Mass Index	26.14±6.01 kg/m2	23.99±5.19 kg/m2	0.04
Systolic Blood Pressure	132.44±19.41 mmHg	122.41±18.17 mmHg	0.01
Diastolic Blood Pressure	79.61±10.51 mmHg	72.92±9.11 mmHg	0.01
VO2 Max	15.21±5.99 mL/kg/min	26.26±6.47 mL/kg/min	<0.001

Metabolic equivalent of task (MET)	4.67±2.12 mL/kg/min	7.89±1.78 mL/kg/min	<0.001
Duke Treadmill Score (DTS)	-3.56±7.89	3.22±8.18	<0.0001

On analyzing the angina index, it was found that mean angina index was 1.14 at baseline and it reduced to 0.45 at week 12 of IRP (p<0.001) [figure 2].

Figure 2: 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 10 (27%) at baseline to 24 patients (65%) 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=37]			
	Low risk (≥5)	Moderate risk (-10 to 4)	Severe risk (≤ -11)	p-value
Baseline	10 (27%)	21 (60%)	6 (16%)	<0.001
Week 12	24 (65%)	11 (30%)	2 (5%)	

On analyzing the dependency on conventional drugs, it was found that overall the consumption of all drug categories was reduced after IRTP therapy. 2 (3%) patients were not taking medications at baseline which increased to 17 patients (19%) after 12 weeks of IRP therapy (table 6).

Table 6: Consumption of Allopathic medication at baseline and post 12 weeks.

Medication	Baseline	After 12 weeks
Angiotensin II receptor blockers	8	3
β-blocker	7	2
Diuretics	2	1
Ca2+ channel blockers	5	2
NSAIDs	8	2
Biguanides	33	20
DPP4	19	10
Sulfonylureas	20	11
Insulin	18	9
Antiplatelets	19	11
Statins	16	9
Nitrates	8	2
No medication	2	12

DISCUSSION:

Despite the wide range of options available for the treatment of IHD, it is still one of the leading providers in diagnosing diseases and mortality rates worldwide. Therefore, it is an urgent need to consider new treatment options for IHD. The traditional class of anti-ischemic drugs has therapeutic benefits in IHD by correcting the imbalance between oxygen demand and cardiac output, lowering blood pressure (BP), lowering platelet aggregation, hypolipidemic action, antioxidant effect, etc. The same substance has been found in various herbal medicines, making Ayurveda a powerful and effective treatment modality for the management of IHD. Panchkarma is treated as an adjunct to the treatment of IHD management, by Ayurvedic doctors.[10] The IRP is a 3-step process involving Snehana, Swedana, and Basti. The potential IRP mode of Snehana- anxiolytic reduces sensitivity to sympathetic activity, Swedana - lowers sodium and fluid-reducing fluids that can help reduce myocardial oxygen demand. Decoction of Tribulus terristris, curcumin and phyllanthrus embelica can help in the release of nitric oxide from endothelium. Along with it can be anti-inflammatory and antioxidant. This action can help improve cardiovascular circulation by causing coronary vasodilation.[10,12,13,14,18,19]

In our analysis of IRP performance in IHD, we found that it showed significant (very high statistical significance) improvement of VO2max, Duke's printing school, DBP, and SBP (high statistical significance) on the 90th day of the complete process. SBP is one of the predictable symptoms of IHD patients. SBP reduction is associated with better prognosis for IHD, because it reduces the loading behind the ventricles and also improves endothelial health.[20] Most importantly, we found that IRP significantly reduced patient dependence on common allopathic drugs at the end of 90 days of treatment.

VO2max measures a high oxygen can be used in exercise. An IHD patient suffers from diastolic dysfunction, which is why VO2max is reduced in such cases indicating that the clinic is reduced in terms of exercise / activity.[21] DTS is used as a diagnostic and diagnostic study for patients at risk of IHD. It is very popular for its risk classification role.

In our study, both VO2max and Duke's most important treadmill points (high statistical significance) were improved. Studies show that the improvement in Duke and VO2max ratio is associated with better prognosis in IHD patients.[15,21,22] Thus, a significant decrease in the value of VO2max and Duke's treadmill after the IRP in our study shows a good prediction of heart disease and death.

In economically disadvantaged countries like India the high reliance on IHD patients on common allopathic drugs raises the cost of health care in many communities. In addition, the increase in the adverse effects of these drugs leads to a decrease in adherence, which further worsens the image.[23] Keeping this in mind, we analyzed changes in the patient's dependence on allopathic drugs by the IRP. There was a significant decrease in dependence on almost the entire class of anti-ischemic drugs, at the end of 90 days, with an increase in the number of patients with allopathic drugs.

Findings from the current study can only be standardized after comparing the findings of other studies with a possible design, large sample size, one arm with only standard treatment and multiple follow-up time. This will help to achieve long-term IRP results in the management of IHD.

CONCLUSION:

There was significant improvement in VO2max, Duke's treadmill score, SBP, DBP after IRP. Also, there was substantive attenuation in patient's dependency on allopathic medications. Hence, IRP may serve as potent and viable alternative to standard allopathic treatment of IHD.

Conflicts of interest: None declared by the authors.

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