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Original Research Article

Role of Ayurveda based non-invasive intervention in management of ischemic heart disease patient of diabetes

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ABSTRACT

Background: The aim of the study was to determine the effectiveness of IRP therapy in patients of myocardial ischemia attending Madhavbaug clinics in Vidarbha region, Maharashtra.
Methods: This was a retrospective study conducted from June 2019 to December 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) of Madhavbaug clinics across 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 patients of IHD were analyzed. At the end of IRP therapy there was statistically significant reduction in weight, BMI, SBP, and DBP. VO2 peak was improved at the end of therapy i.e. 26.51±5.93 ml/kg/min as compared to baseline i.e.; 15.62±5.36 ml/kg/min and the difference was highly statistically significant ($p<0.001$). DTS improved from -2.93±5.88 at baseline to 3.21±6.03 at week 12 of IRP therapy and the difference was highly statistically significant ($p<0.0001$).
Conclusions: Findings of present study suggest that IRP can serve as effective therapeutic option for the management of myocardial ischemia.

Keywords: Ischemic heart disease, Ischemia reversal program, Ayurveda, Panchkarma, VO2 peak, Dukes treadmill score

INTRODUCTION

Cardiovascular diseases (CVDs) including cardiovascular disease in the form of Ischemic heart disease (IHD) have increased the prevalence of epidemic figures. About 17.5 million deaths worldwide are due to CVD.[1] The sad reality is that only a quarter of these deaths are in the developing world. This is further complicated by the fact that, although the increase in deaths from CVD is declining in developed countries, it poses a threat to developing countries such as India, year after year.[2] Epidemiological changes are being attributed to other authors in this growing trend, which includes urban migration, lifestyle changes, etc. India is experiencing years of obesity and unemployment, with sedentary lifestyle exacerbating diseases such as lipid fever, diabetes, IHD, HTN, which in turn exacerbates India's morbidity and mortality, contributing to the increasing burden of health care and costs. A study by the Global Burden of Disease found that over the past three decades there has been a recurrence of the disease and death due to CVD.[3] The death toll from IHD has risen from 0.61 million in 1990 to 1.13 million in

2010, a worrying fact. According to a World Health Organization report, India will spend $237 billion, on direct spending on health care and indirectly due to product losses due to IHD.[4]

IHD contributes significantly to deaths due to CVD in India (>80%). This death rate is much higher than the global mortality rate due to IHD. In India, IHD causes the cause of 1/5 of all deaths (21%) and 1/10 of the years of lost life, which equates premature mortality by looking at young deaths due to old age.[5] Moreover, IHD is reported to be associated with Diabetes mellitus (DM) and this association ranges from 1.5 to 21%.[6] At risk, diabetes, and its predominant condition, Type 2 diabetes mellitus (T2DM), has a different association with CHD. Those with diabetes are two to four times more likely to develop coronary heart disease than people without diabetes, and CVD accounts for 65-75 percent of deaths in people with diabetes. These surprising findings regarding high risk of death have led to suspicions that common precursors prioritize diabetes and CHD and the following effects of insulin resistance, visceral adiposity, as well as excessive inflammation are subject to the pathophysiology of thrombogenesis.[7]

Low availability rates, low adherence, reduced treatment adherence, low use of evidence-based implants are major barriers to the effective use of cost-effective treatment on a large scale, in India. Improper adherence to medication, in itself, is a major factor contributing to the increase in morbidity and mortality in patients with IHD and also increases the cost of health care.[8] Although there are various guidelines available for combating the risk of IHD, there is still an increase. This is complicated by low adherence to medications, due to adverse effects on medications, increased costs, etc.[8] Therefore, there is a need to explore new treatment options to effectively combat IHD.

The management of IHD is complex due to the role of the various factory when deciding on a treatment plan such as comorbidities, age, complementary medications, etc. Therefore, it is important to look for a time to search for a novel where one will help reduce anxiety and fear again with IHD and increase the quality of life at the same time.[4] The therapeutic role of drugs used in the treatment of IHD is due to the correction of the imbalance between oxygen demand and cardiovascular supply, reduced Blood pressure (BP), reduced platelet aggregation, hypolipidemic action, antioxidant effect, etc.[9] Similar action has been found in many herbal remedies, which serve as potential therapies for new HTN therapies.[10]

Ayurveda medical practice promotes the use of traditional medicine in the critical stage of the disease, while adding 'panchkarma' therapy (internal cleansing through a multi-step process) to the chronic stage of the disease. The Ischemia reversal program (IRP) is a combination of panchkarma and allied therapy. The techniques used in panchkarma under this program are Swedana i.e. heat treatment, Snehana e.g. Oleation and Basti which means per rectal administration of herbal drugs. These methods are well-known for their detoxification function.[4] It has been found in research that IHD is associated with anxiety, depression, diminished sense of well-being, reduced quality of life, and so on.[11,12] Therefore, we have conducted a retrospective study to investigate the effectiveness of the IRP, as an adjunct to standard treatment versus the treatment of IHD patients with DM. We tested the effect of IRP on high oxygen consumption / high aerobic dose measured by VO_2max (V-volume, O_2-oxygen, max-maximum), Duke's school treadmill, Systolic (SBP) and Diastolic BP (DBP), and the dependence of this on IHD patients on standard medications.

METHODS

This was a retrospective study conducted at Out-patient departments (OPDs) of Madhavbaug clinics across India. Study period was from April 2019 to January 2020, wherein we identified the data of patients suffering from IHD (positive for inducible ischemia from stress test) and diabetes mellitus of either gender or any age. The data of patients who had been administered IRP with minimum 7 sittings over a span of 12 weeks were considered for the study. The patient records wherein complete treatment and follow up details were not available or treatment was changes were excluded from analysis. 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. Based on previous published study sample seize was taken as 130.[4] The IRP is a 3-steps 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.[4]

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.[14] 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:

$$\begin{aligned} &Duke\ treadmill\ score \\ &\quad = maximum\ exercise\ (\text{min}) \\ &\quad - [5 \times ST\ segment\ deviation\ (mm)] \\ &\quad - (4 \times angina\ index) \end{aligned}$$

where 0=no angina, 1=non-limiting angina, 2=exercise limiting angina.[14] 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.[14]

The maximum volume of oxygen that an individual can consume during intense, whole-body exercise is called as VO_2max/maximal aerobic capacity (ml/kg/min).[15]

A Metabolic equivalent (MET) is defined as the amount of oxygen consumed by an individual at rest (also known as resting energy expenditure) i.e.; approximately 3.5 ml O_2/kg/min.[16] Based on HbA1c levels after CDC therapy the patients were categorized as: (a) controlled- HbA1c <5.7; (b) borderline- HbA1c 5.7-6.5; and (c) uncontrolled- HbA1c>6.5.

Ethical considerations

Since the present study was record based retrospective evaluation, ethics committee approval was not taken. Although patient confidentiality was maintained throughout the study period in accordance with Declaration of Helsinki.

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.

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 min
Swedana	Passive heat therapy	Dashmoola (group of ten herbal roots) with steam at ≤40˚C)	10-15 min+ 3-4 min of relaxation after procedure
Basti	Per rectal drug administration using a rectal solution.	Luke-warm GHA decoction 100 ml	15 min

Note: GHA stands for Gokshura/Tribulus terrestris (antihypertensive action, antispasmodic, hypolipidemic, cardioprotective actions); Haridra/Curcuma longa (hypotensive, anticoagulant, antioxidant); Amalaki/Emblica officinalis (cardioprotective, hypolipidemic, antioxidant).[13]

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

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

RESULTS

Study population

A total of 130 patient's data was screened for inclusion in the study. However, based on the availability of data (ay 1 and day 90) and the inclusion criteria, 121 patients were selected, and their data was considered for analysis (Figure 1). The baseline characteristics of these patients are shown in Table 3.

At the end of IRP therapy there was statistically significant reduction in weight as compared (64.46±13.61 kg) to baseline (68.21±11.57 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. 25.87±7.19 ml/kg/min as compared to baseline i.e. 16.35±6.89 ml/kg/min and the difference was highly statistically significant (p<0.001). DTS improved from -3.11±8.41 at baseline to 3.57±8.34 at week 12 of IRP therapy and the difference was highly statistically significant (p<0.0001) (Table 4). Mean HbA1c was reduced from 7.88 at baseline to 6.57 after 12 weeks of IRP therapy. This difference was highly statistically significant (p<0.001) (Figure 2). On analyzing the DTS, number of patients in low risk category increased from 14 (30%) at baseline to 28 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) (Figure 3).

At the end of 12 weeks, 39 patients were having controlled DM i.e.; HbA1c<5.7, 58 and 24 in borderline and uncontrolled DM categories, respectively.

On analyzing improvement in VO_2 max and DTS across categories of status of DM at the end of 12 weeks IRP therapy, it was found that greater improvement in VO_2 max and DTS was seen in controlled DM as compared to borderline and least in uncontrolled DM patients. The difference was highly statistically significant with p<0.001 (Table 5).

On analyzing the dependency on conventional drugs, it was found that overall the consumption of all drug categories was reduced after IRTP therapy.

3 (2.4%) patients were not taking medications at baseline which increased to 22 patients (19%) after 12 weeks of IRP therapy (Table 6).

Table 3: Baseline characteristics of the study subjects (N=121).

Variables	N = 121
Age (years) (mean±SD)	61.21±11.27
Gender	
Male	45 (57%)
Female	33 (43%)

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

Parameters	Baseline	After 12 weeks
Weight (kg)	68.21±11.57	64.46±13.61
Body mass index (kg/m^2)	27.21±5.22	23.71±4.89
Abdominal girth	93.76 ± 11.29	87.25 ± 10.33
Systolic blood pressure (mmHg)	131.07±17.62	123.58±14.92
Diastolic blood pressure (mmHg)	79.21±8.86	73.12±9.38
VO_2 max	16.35±6.89	25.87±7.19
Metabolic equivalent of task (MET) (ml/kg/min)	4.88±2.23	7.37±2.27
Duke treadmill score (DTS)	-3.11±8.41	3.57±8.34

Table 5: Changes in VO_2 max and Duke's trade mill score (DTS) at the end of 12 weeks IRP therapy in patients of present study.

DM	ΔVO_2 max	ΔDTS
Controlled (HbA1c <5.7) (N=39)	11.12±5.12	6.57±2.14
Borderline (5.6-6.5) (N=58)	8.56±6.01	4.24±2.76
Uncontrolled (>6.5) (N=24)	7.02±4.23	3.89±1.99
P value	<0.001	<0.001

Note: ΔVO_2 max=VO_2 max$_{12week}$–VO_2max$_{baseline}$; ΔDTS= DTS$_{12week}$ – DTS$_{baseline}$.

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

Medications	Baseline
Angiotensin II receptor blockers	10
β-blocker	11
Diuretics	3
Ca_2+ channel blockers	12
NSAIDs	8
Biguanides	56
DPP4	21
Sulfonylureas	39
Insulin	22
Antiplatelets	21
Statins	19
Nitrates	13
No medication	3

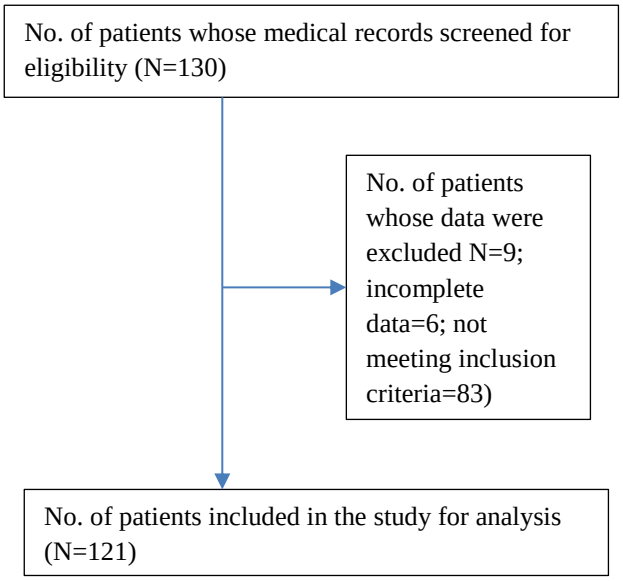

Figure 1: Patient enrolment flow chart.

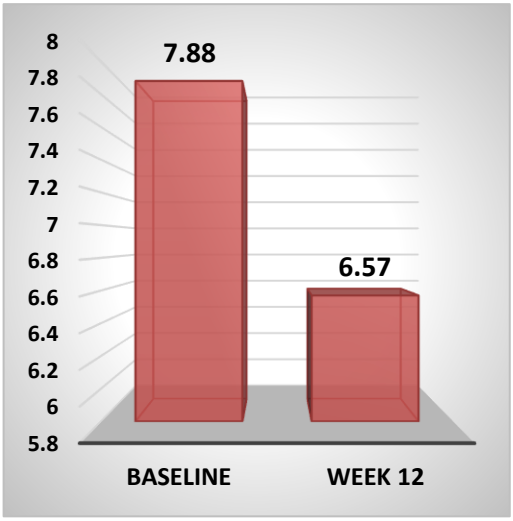

Figure 2: Mean glycosylated hemoglobin (HbA1c) in the patients of present study.

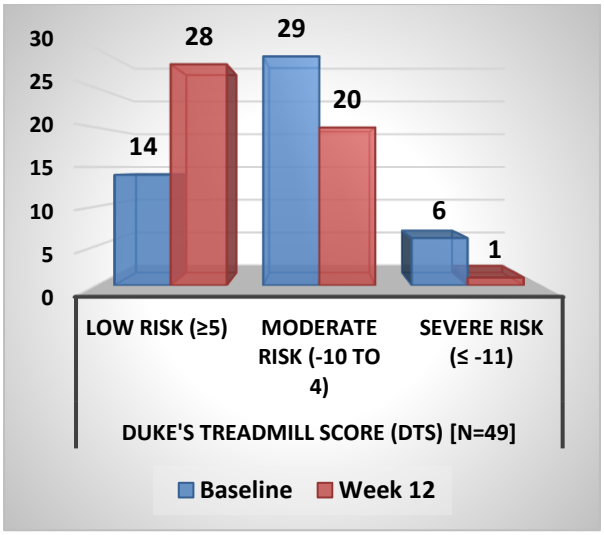

Figure 3: Duke's trade mill score in patients of the present study.

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 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.[4]

The IRP is a 3-step process involving Snehana, Swedana, and Basti. The potential IRP mode of Snehana- anxiolytic reduces sensitivity to sympathetic over 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, it can act as anti-inflammatory and antioxidant. This action can help improve cardiovascular circulation by causing coronary vasodilation.[4] In our analysis of IRP performance in IHD, we found that it showed significant (very high statistical significance) improvement of VO_2max, 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.[18] Most importantly, we found that IRP significantly reduced patient dependence on common allopathic drugs at the end of 90 days of treatment.

VO_2max measures a high oxygen can be used in exercise. An IHD patient suffers from diastolic dysfunction, which is why VO_2max is reduced in such cases indicating that the clinic is reduced in terms of exercise/activity.[19] Duke's treadmill score 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 VO_2max and Duke's most important treadmill points (high statistical significance) were improved. Studies show that the improvement in Duke and VO_2max ratio is associated with better prognosis in IHD patients.[20] Thus, a significant decrease in the value of VO_2max and Duke's treadmill after the IRP in our study shows a good prediction of heart disease and death.

On analyzing the VO_2 max and DTS improvement and DM control after IRP therapy, it was found that controlled DM patients had better improvement in both the parameters as compared to borderline and uncontrolled DM. DM is implicated to augment thrombogenesis via insulin resistance, visceral adiposity, and excess inflammation, oxidative stress, increased atherogenecity of cholesterol, abnormal vascular reactivity, augmented hemostatic activation. Basti, in particular is known to reduce the adipogenesis, has hypolipidemic action and these actions are thought to control the HbA1c.[21] Thus, reduction in HbA1c with IRP along with improvement on ischemia related parameters is a welcome sign in patients of IHD.

In economically challenged 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.[22] 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 VO_2max, Duke's treadmill score, SBP, DBP along with improvement on HbA1c 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 in diabetic patients.

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