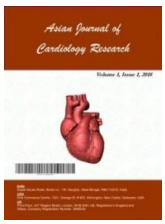

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Efficacy of Ischemia Reversal Program (IRP) in Elderly Patients of Ischemic Heart Disease with Known History of Hypertension

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Authors' contributions

This work was carried out in collaboration between all authors. All authors read and approved the final manuscript.

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Original Research Article

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ABSTRACT

Context: The prevalence figures of major cardiovascular diseases (CVDs)- Ischemic heart diseases (IHD) and Hypertension (HTN) have escalated to epidemic levels, in both developing and developed countries. Ischemia Reversal Program (IRP) is a combination of Panchakarma and allied therapy.
Aims: This study was conducted to evaluate the effect of IRP on VO2max, Duke's Treadmill Score, systolic blood pressure (SBP), diastolic blood pressure (DBP) in IHD patients with known history of HTN.

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Setting and Design: This observational study was conducted from January 2017 to January 2018, wherein the data of IHD patients (inducible ischemia on stress testing) with history of HTN, who attended out-patient departments (OPDs) at Madhavbaug clinics in Maharashtra, India were identified.

Materials and Methods: Data of patients who were administered IRP (60-75 minutes) with minimum 7 sittings over 90 days (± 15 days) were considered. Variables were compared between day 1 and day 90 of IRP.

Results: Out of 30 enrolled patients, 24 were males while 6 females. There was a significant improvement in Duke's score with subjects at moderate (43.3 %) and high (46.7 %) risk at baseline were significantly decreased to low (50 %) and moderate (50 %) after 90th day of therapy. IRP also showed significant improvement in VO2max from 18.14 ± 7.82 to 27.88 ± 7.31; $p<0.001$), SBP from 133.5 ± 16.36 to 121.87 ± 11.67, $p< 0.004$), DBP from 79.53 ± 8.53 to 75.3 ± 8.09, $p< 0.05$). Dependency on concomitant medicines was reduced. Number of patients not taking any conventional medicine increased from 10% at day 1 to 27% at day 90 of IRP.

Conclusion: IRP was effective in management of elderly IHD patients with history of hypertension; it had triple benefits i.e. anti-ischemic effect, as well as reducing the blood pressure and reducing the dependency on conventional medications, which carries favourable prognosis.

Keywords: Ischemia reversal program; IRP; Panchakarma; ischemic heart disease; IHD; blood pressure; hypertension.

1. INTRODUCTION

The prevalence figures of major cardiovascular diseases (CVDs)- ischemic heart diseases (IHD) and hypertension (HTN) have escalated to epidemic levels, in both developing and developed countries. This figures have been reflected in 18 million deaths, in global study [1]. Findings of various studies have established HTN as major conventional risk factor for IHD in plethora of population across the world [2,3]. This epidemiological finding is corroborated by the postulation that HTN, via common pathogenesis with atherosclerosis i.e. oxidative damage and inflammation of arterial wall, may increase IHD [4,5]. It is projected that more than 80% of deaths due to CVDs can be attributed to IHD and HTN [6,7]. Rising incidence of sedentary lifestyle, owing to routine inactivity and obesity in India has led to increased morbidity and mortality due to acquirement of diseases like IHD, HTN, diabetes, lipid abnormalities, etc. [8]. Deaths due to IHD and HTN alone have witnessed an increase by a mighty margin of more than half million in past 2 decades [9].

Despite availability of cost effective therapeutic options in India, numerous factors like less awareness of the disease in general population, low diagnosis rates, low adherence rates, less use of evidence based therapeutic options, have been the foremost obstacles in optimal use of these resources. Out of these, one major challenge has been reduced patient adherence to conventional therapy. The prevalence of IHD and HTN is rising, despite availability of extensive guidelines on the management of IHD and HTN [10,11]. Moreover, there is complex interplay of various factors in the management of IHD with HTN like age, comorbid diseases, other medications, etc. Therefore, it is essential mandate of the hour to explore new therapeutic options, which will help to normalise the quality of life by decreasing apprehension and dread in patients suffering from IHD with HTN [12].

Conventional drugs used in the treatment of IHD with HTN act by reducing the blood pressure (BP), maintenance of balance between oxygen demand and supply of the heart, antioxidant effect, normalisation of raised lipid levels, prevention of platelet aggregation. Since analogous activity has been found in various herbal drugs in clinical studies, these drugs can quench the exploratory search for the novel therapeutic option for treatment of IHD in hypertensive patients [13,14,15]. Most prominent and effective technique in the armamentarium of Ayurvedic medicine is Panchakarma, which restores the internal bodily balance. It comprises broadly of use of herbally extracted oils, steam therapy, massage therapy, nasal therapy, vomiting therapy, enema and purgation therapies. The main aim of panchakarma is to detoxify the body which allows smooth coordination of various organs systems like cardiovascular, respiratory, nervous and digestive system. Advantages of panchakarma are reduction in anxiety, stress, energetic feeling in subjects, and improved quality of life. The only

disadvantage is that some beneficial effects of panchakarma takes time to take effect [16]. Panchakarma, a multi-step therapy for internal purification of body, is advocated in chronic phase of disease, as per Ayurvedic Science of Medicine. Ischemia reversal program (IRP) combines Panchakarma with diet therapy for treatment of IHD with HTN. Snehana i.e. oleation, Swedana i.e. passive heat therapy and Basti i.e. per rectal drug administration are the three techniques used in Panchakarma, as a part of this program, which is extensively used for detoxification of body [17,18]. Given the fact that depression, reduced feeling of internal strength, reduced quality of life, and anxiety are significantly associated with HTN and IHD [19,20]; we planned the present study to assess the effect of IRP in patients of IHD with HTN. 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, systolic (SBP) and diastolic BP (DBP), and dependency of these IHD patients on standard conventional medications.

2. MATERIALS AND METHODS

The present study was record based retrospective survey of 1 year, from January 2017 to January 2018. The study site was Madhavbaug clinics outpatient department (OPDs) located in various cities across Maharashtra state. We included elderly patients (age ≥ 60 years) suffering with IHD (positive stress test) and known history of HTN, irrespective of sex. Out of above mentioned patients, those patients were selected for analysis who were given IRP of minimum 7 sittings for 90 ± 15 days. The patients followed diet chart/plan of 1000-1200 kcal/day.

Only those patients were finally included wherein complete data of patient from day 1 to day 90 of IRP was available from OPDs of Madhavbaug clinics located across various cities in Maharashtra state.

According to medical records, patients were advised to have light breakfast followed by 3 step IRP. One sitting of the procedure took 65-75 minutes, as described in Table 1 [21].

On day 1 of IRP, the patients had undergone Duke's treadmill scoring, VO2max, SBP, DBP as per international recommendations [25]. These readings were considered as baseline readings. This process was repeated on day 90 of IRP to analyse change from baseline reading. According to medical records, the patients followed diet chart/plan of 1000-1200 kcal/day.

2.1 Statistical Analysis

Data was pooled from medical records of the patients and coded in Microsoft Excel spreadsheet. R Version 3.4.1 software was used to analyse the data. Data was non-normal so non parametric test were used". 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 90 days of treatment. Wilcoxon signed rank test was used to assess the difference between baseline values and 90th day 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 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) [22,23,24]

3. RESULTS

3.1 Study Population

Demographic characteristics of the patients enrolled in the study was as shown in Table 2. The present study involved a total of 30 elderly patients of IHD with known history of HTN. The mean age of the patients was 64.33 ± 3.71 years with male predominance (80%). Almost 50% were having past medical history of DM and IHD (Fig. 1).

Comparison of Duke's treadmill score baseline and after 90 days of treatment is as shown in Table 3. On the first day of the treatment almost all the study patients were in the moderate and high-risk category score but after 90 days of treatment none of patients were at the high risk (Fig. 2). The patients at moderate (43.3 %) and high (46.7 %) risk were significantly seen in low (50 %) and moderate (50 %) category after 90 days of treatment. Overall the result shows the treatment was effective.

Clinical parameters compared between baseline values and after 90th day was as shown in Table 4. The maximum amount of oxygen consumption was significantly improved after 90 days of treatment (P < 0.001). On the first day of the treatment half of the patients were with low amount of VO2 max (6- 17) and after 90 days of treatment the range (15- 27) was significantly improved (Fig. 3.1). Systolic blood pressure significantly reached near normal value after 90 days of treatment (P =0.004) (Fig. 3.2). Diastolic blood pressure which was normal before the treatment reduced significantly (Fig. 3.3), however it was within the normal range (P =0.03).

Table 2. Demographic characteristic of the study patients (n=30)

Variable	n=30
Age (Years)	64.33 ± 3.71
Gender n(%)	
Male	24 (80%)
Female	6 (20%)
Past medical history n(%)	
DM	16 (53.3)
CAD	5 (16.7)
IHD	13 (43.3)
MI	4 (13.3)
Past surgical history n(%)	
Angiography	4 (13.3)
CABG	3 (10)
PTCA	3 (10)

Data were expressed in % and mean ± SD
DM; Diabetes Mellitus, CAD; Coronary Artery Disease, IHD; Ischemic Heart disease, MI; Myocardial Infarction, CABG; Coronary artery bypass grafting, PTCA; Percutaneous transluminal coronary angioplasty

Dependency on conventional medicines reduced significantly after 90 days of IRP, in all drug class, with greatest reduction in ARB, anti-anginal, CCB drug. Number of patients not taking any conventional medicine increased from 10% at day 1 to 27% at day 90 of IRP (Table 5, Fig. 4).

Table 3. Comparison of Duke's treadmill score baseline and after 90 days of treatment (n=30)

Category	Duke Treadmill Score		p-value
	Baseline	After 90 days	
Low	3 (10%)	15 (50%)	<0.001*
Moderate	13 (43.3%)	15 (50%)	
Hight	14 (46.7%)	0	

** indicates high statistically significant improvement*

Table 4. Comparison of clinical parameters between baseline values and 90th day

Variable n=30	Baseline	After 90 days	p value
VO2max	18.14 ± 7.82	27.88 ± 7.31	<0.001
SBP	133.5 ± 16.36	121.87 ± 11.67	0.004
DBP	79.53 ± 8.53	75.3 ± 8.09	0.03

VO2.max, Maximum amount of oxygen consumption; SBP, Systolic blood pressure; DBP, Diastolic blood pressure

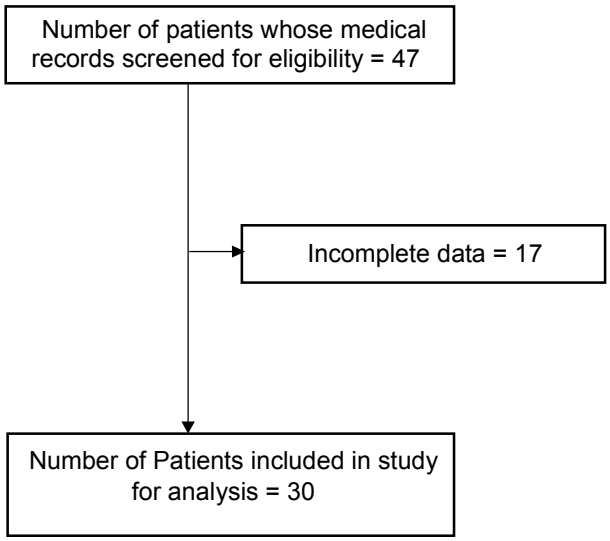

Fig. 1. Patient enrolment flow chart

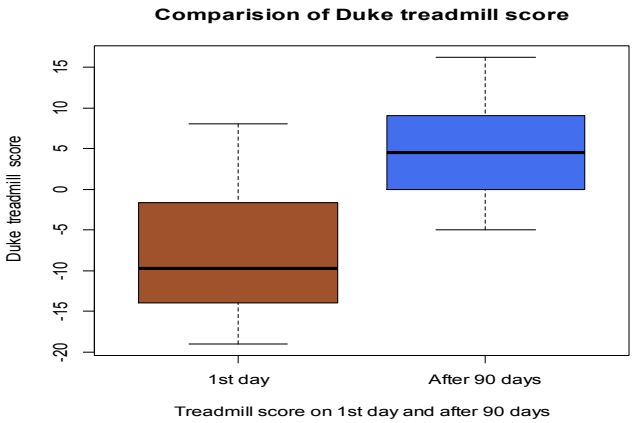

Fig. 2. Comparison of Duke treadmill score baseline and after 90 days of treatment (n=30)

Table 5. Allopathy medicine consumption at the baseline and after 90 days

Medicine	Baseline	After 90 days
NSAID	13 (43.33)	12 (40)
ARB	12 (40)	9 (30)
Anti-platelet	9 (30)	10 (33.33)
Anti-anginal	3 (10)	0 (0)
Beta blocker	10 (33.33)	11 (36.67)
CCB	5 (16.67)	3 (10)
Statin	10 (33.33)	7 (23.33)
Diuretic	6 (20)	3 (10)
ACE	6 (20)	5 (16.67)
Biguanide	10 (33.33)	10 (33.33)
Sulfonylurea	8 (26.67)	8 (26.67)
No Medicine	3 (10)	8 (26.67)

4. DISCUSSION

IHD and HTN are the major culprit of global morbidity and mortality, even though there are plenty of therapeutic options available for the same. Thus, it is desperate requirement of the current time to look out for novel therapeutic option for management of IHD with HTN. Conventional drugs used for treatment of IHD with HTN act by rectifying mismatch between oxygen demand and supply of the heart, hypolipidemic action, antioxidant effect, reduction in BP. Ayurveda can serve as a promising therapeutic option for IHD with HTN, since many herbal drugs have been found to possess therapeutic action similar to that of conventional drugs. Ayurveda physicians give Panchakarma

therapy in the management of IHD with HTN [21]. Three-step Panchakarma in the form of Swedana, Snehana and Basti is administered to the patients of IHD with history of HTN, as a part of IRP along with diet therapy of 1000-1200 kcal/day. IRP might act by reducing the sympathetic overactivity (reduce BP) via anxiolytic action of Snehana, reduction of myocardial oxygen demand via reduction of sodium and water load (preload of heart) by Swedana and Basti helps in release of nitric oxide from vascular endothelium, which is coronary vasodilator, anti-inflammatory and antioxidant actions through decoction by Gokshura i.e. Tribulus terrestris, Haridra i.e. Curcuma longa, and Amalaki i.e. Emblica officnalis. They also help in improving coronary circulation [17,22,23,24]. With the aim of scrutinising the effect of IRP in IHD with HTN, it was seen that there was very high statistically significant improvement in VO2max, Duke's treadmill score, SBP and highly statistically significant improvement in DBP at the end of 90th day of whole procedure. Since DBP and SBP are one of the prognosticators in IHD, significant reduction in both in our present study indicates good prognosis since reduction in SBP and DBP reduces afterload of the ventricles, thus reducing oxygen demand of the heart [26].

Maximum oxygen utilisation capacity in rigorous physical activities is measured by VO2max. It is reduced in hypertensive IHD patients due to diastolic dysfunction, which clinically presents as reduced work capacity [27]. Due to its risk stratification role, in addition to diagnostic and prognostic tool, Duke's treadmill score has high significance in patients of IHD and HTN. Score < -11 indicates high risk group, who need coronary angiography with a 4 year survival rate of less than 80%. Score between -10 to +4 indicates intermediate risk group, who need either myocardial perfusion scan or coronary angiography, depending on general condition of the patient. Score of > +5 indicates low risk group , who do not need any invasive investigation for further evaluation and their 4 year survival rate is 100% [27].

In our study VO2max, Duke's score, SBP and DBP were significantly improved towards normal levels. Similar Studies have shown that improvement in these parameters is associated with better prognosis in patients of IHD with history of HTN [27,28]. Hence, findings of our present study suggests a reduction in these parameters should be associated with a reduction in cardiovascular morbidity and mortality. However, other such studies should be done on national scale, probably with greater sample size, 2 treatment arms to facilitate direct comparison with standard therapy, more follow up period, so that findings of our study can be generalised for larger population.

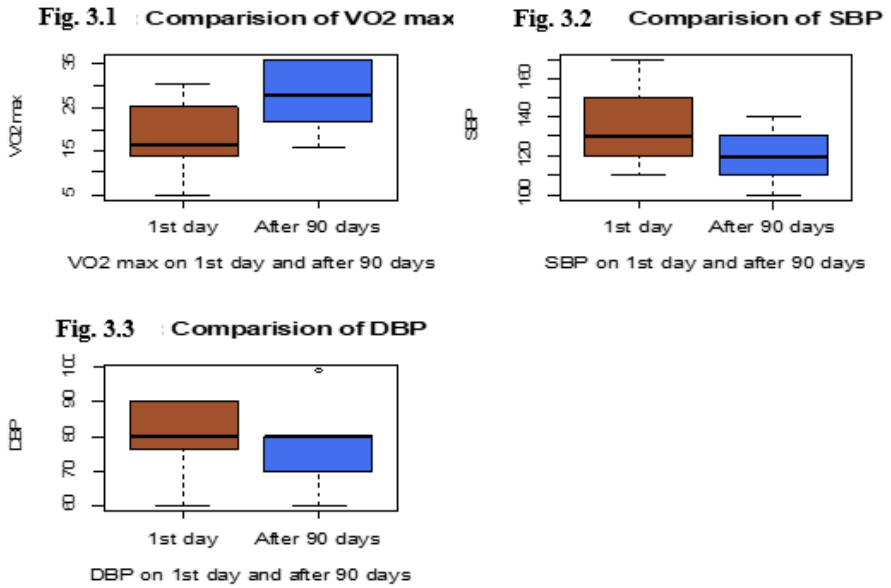

Fig. 3. Comparison of consumption of allopathy medicine at 1st day and after 90 days

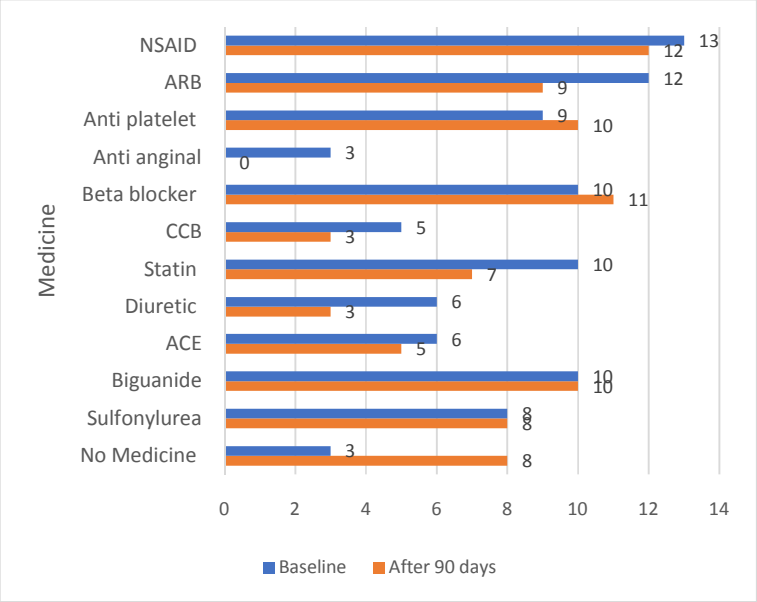

Fig. 4. Allopathy medicine consumption at the baseline and after 90 days

5. CONCLUSION

Findings of our study suggests that IRP can serve as novel therapeutic option for treatment of IHD in patients with HTN since it significantly reduces VO2max, Duke's score, SBP and DBP. Also, it significantly reduces dependency on conventional medications, which is added benefit in such patients.

CONSENT

As per international standard or university standard, patients written consent has been collected and preserved by the author(s).

ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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