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Ischemic Reversal Program (IRP) is designed for improving the blood flow to heart. Lack of blood supply to the heart can often cause of heart attacks and is common in people with high blood pressure. IRP aims to reduce the risk of heart attack and increase exercise tolerance levels to improve quality of life. IRP treatment is associated with significant improvement in the Duke Treadmill score and VO_2 max, thereby leading to betterment of prognosis in IHD patients. The dependency on conventional medicines was also decreased by IRP.

Sane et al.

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Original Article

Ischemia Reversal Program (IRP) in patients suffering from Ischemic Heart Disease (IHD) with known history of Hypertension: A Retrospective Study

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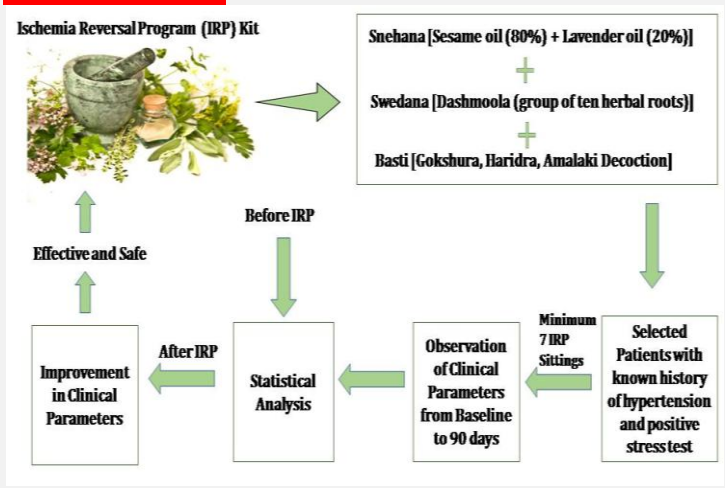
ABSTRACT

Introduction: Cardiovascular mortality has risen in the last few years and Ischemic Heart Disease (IHD) is one of the most common causes. Ischemia Reversal Program (IRP) kit uses a combination of *Snehana* (Centripetal oleation), *Swedana* (Thermal vasodilation) and *Basti* (Per rectal drug administration) for providing relief to IHD patients. This study was conducted to evaluate the efficacy of IRP in IHD patients. ***Methods***: This retrospective study included data of patients having positive inducible ischemia by stress test with known history of hypertension (HTN) and had visited the *Madhavbaug clinics*. A minimum of 7 IRP sittings were needed for inclusion. Duke Treadmill score, VO_2 max, systolic plus diastolic blood pressure (SBP, DBP) and details of conventional medications were noted on day 1 and on day 90 followed by comparison between these values. ***Results***: 19 patients having mean age 59.26 ± 8.03 years were enrolled, with 78.9% being males. On day 90, none of the patients were at high risk by Duke Treadmill Score, compared to 47.4% being at high risk on day 1 ($p<0.01$). Mean VO_2 max significantly increased on day 90 of IRP therapy ($p<0.01$) while mean SBP and DBP decreased, though not significantly ($p>0.05$). The number of subjects on allopathic medicines decreased after 90th day, as compared to day 1. ***Conclusion***: IRP treatment is associated with significant improvement in the Duke Treadmill score and VO_2 max, thereby leading to betterment of prognosis in IHD patients. The dependency on conventional medicines was also decreased by IRP.

KEYWORDS Coronary artery disease, Duke's Treadmill test, Ischemia Reversal Program, Myocardial ischemia.

PICTORIAL ABSTRACT



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1. INTRODUCTION

Cardiovascular disorders are now assumed to have become an epidemic worldwide. Although the cardiovascular mortality is reduced in developing countries, it is on a rise in developing countries like India[1]. It is estimated that 75% of cardiovascular deaths occur in developing countries like India. The main culprit for cardiovascular mortality is coronary heart disease (CHD), also known as Ischemic Heart Disease (IHD). The increase in the prevalence of IHD is attributable to various factors like urbanization, industrialization and major lifestyle changes[2]. A growing trend in cardiovascular disease related mortality has been reported from India, with 20.6% deaths in 1990, 21.4% in 1995, 24.3% in 2000, 27.5% in 2005, and 29.0% in 2013[3]. It is estimated that the prevalence of IHD in India has grown from 2% in 1960 to about 14% in 2013[4]. Another important factor, which has led to the increase in cases of IHD and other cardiovascular disorders is the presence of uncontrolled hypertension (HTN) in the population. WHO has estimated that out of the deaths occurring due to cardiovascular disease, 16% of IHD related deaths are because of HTN[5].

The current treatment algorithm for IHD and HTN comprises of lifestyle modifications and pharmacotherapy. Drugs belonging to classes of angiotensin converting enzyme (ACE) inhibitors, calcium channel blockers (CCBs), and beta blockers have been used to control both IHD and HTN. Specific treatment for IHD also includes the use of anti-platelet agents like aspirin as well as anti-dyslipidemic drugs like statins. However, despite the presence of multiple drugs in their treatment, there is an unmet need for the management of IHD and HTN, which is evident by the growing prevalence. Another drawback is the occurrence of

multiple adverse effects with the currently available allopathic drugs. Thus, there is undoubtedly a strong need to discover safer and cost-effective options for the treatment of IHD as well as HTN.

Ayurveda is the Indian traditional system of medicine, which is being used by multiple physicians to treat and manage various diseases. Panchakarma and allied therapies are used by Ayurvedic physicians to provide relief to patients suffering from numerous disorders and one such integrative way of managing IHD patients is by using Ischemia Reversal Program (IRP) Kit. This IRP kit uses a combination of *Snehana* (Centripetal oleation), *Swedana* (Thermal vasodilation) and *Basti* (Per rectal drug administration) for providing relief to IHD patients. Though, IRP is being used in practice by physicians with success, research evidences are lacking. Ayurvedic interventions have not been assessed methodically for their possible beneficial effects in the treatment of IHD. Hence, this study was planned to assess the efficacy of IRP kit in IHD patients with known history of HTN.

The functional capacity of an individual denotes his ability to perform exertional activities. IHD is associated with impaired functional capacity, indicated by a compromise in the maximum aerobic capacity (MAC), also known as VO_2 max. The cardiorespiratory fitness of an individual is denoted by VO_2 max, whose improvement is associated with better CHD outcome.[6] Hence, a study was planned to evaluate the VO_2 max and the Duke treadmill score of the patients of IHD on IRP. It was also planned to assess the effect of IRP on blood pressure (BP) and to see whether there was any decrease in the conventional medications' intake.

2. MATERIALS AND METHODS

This observational retrospective study was planned for patients between the periods March 2017 to February 2018. Data of patients having positive inducible ischemia by stress test with known history of HTN and had visited the *Madhavbaug Clinics* were considered for the study. The data of patients who had been administered the IRP kit with minimum of 7 sittings over a 90-day period was considered for the study. Cases were identified, and data were analyzed from the records of *Madhavbaug* clinics retrospectively. The selection was based upon the availability of complete relevant baseline data (day 1 of IRP) and final day data (day 90 of IRP) of the patients. The information about prescribed concomitant medicines or co-morbidities, if any, was also noted down. All the patients who received the IRP were on a standard diet of 1200 calories/day.

The IRP is a 3-step procedure, which is a combination of Panchakarma and allied therapies. IRP uses various decoctions and oils, which have been described in table 1. *Snehana* is a 30-35 minutes procedure, which involves *Lavender oil*-based decoction, to be administered by external massage to the IHD patients. This massage technique uses centripetal or upward strokes directed towards the heart. *Swedana* or passive heat therapy is a 10 -15 minutes procedure, which involves directing the IHD patients to lie in a supine position inside a sudation box, with their head positioned outside the box. *Dashamoola* (group of ten herbs) steam of temperature not more than 40 degrees is then passed steadily for 10-15 minutes. After the treatment, patients were asked to relax for 3-4 minutes. *Basti* is the procedure of per-rectal drug administration for a period of 15 minutes to the IHD patients using *Tribulus terrestris, Curcuma longa* and *Emblica officinalis* decoction.

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	*Dashamoola* (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 *Gokshura- Tribulus terrestris* Linn. *(Zygophyllaceae)* *Haridra- Curcuma longa* Linn. *(Zingiberaceae)* *Amalaki- Emblica officinalis* L.	15 minutes

Table 2. Score chart for the Duke Treadmill scores

Duke Treadmill Score and Level of Risk	
Score range	**Level of Risk**
Greater or equal to +5	Low Risk
+4 to -10	Moderate Risk
≤ - 11	High Risk

Segment deviation (depression or elevation), and exercise-induced angina. The formula used for the same is:

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.

A Duke Treadmill score ⩾5 indicates low risk for cardiovascular events (predicted 4-year survival was 99%). This population does not need further investigation with coronary angiography. A score ≤ -11 indicates high risk for cardiovascular events (predicted 4-year survival was 79%). 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.[7] We calculated the Duke Treadmill score and classified the patients, according to the risk for cardiovascular events, on day 1 and day 90 of the study.

On day 1 of the IRP, the patients had undergone cardiac stress testing by 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 peak VO_2 max. This process was repeated on day 90 of the IRP to calculate VO_2 max.

The maximum work load was assessed in terms of metabolic equivalents (METs) and this was multiplied by 3.5 to give peak VO_2 max, which is nothing but MAC. This process was repeated on day 90 of the IRP to calculate MAC.

The other baseline and day-90 data which were considered retrospectively by investigators for the inclusion of the patients included the SBP, DBP and the conventional treatment information. The dependency on standard medication was calculated both on day 1 and day 90 of IRP as the percentage of patients out of the total enrolled ones who required a conventional allopathic therapeutic agent during the study period of 90 days.

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. The McNemar-Bowker test was used to assess Duke Treadmill Score before and after 90 days of treatment. The paired t-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.

3. RESULTS AND DISCUSSION

3.1 Study population

A total of 24 patients' data was screened for inclusion in the study. However, based on the availability of data (Day 1 and Day 90), 19 patients were selected, and their data were considered for analysis (Figure 1). The baseline characteristics of these patients are shown in table 3. The mean age of the enrolled subjects was 59.26 ± 8.03 years. Nearly three-fourths of the study subjects were males (78.9 %). When the co-morbidity profile was assessed, 36.84% subjects had coronary artery disease (CAD) and 15.79% subjects had obesity. All the patients approached *Panchakarma* unit for *Swedana* during the study period.

Figure 1. Patient Enrolment Flow Chart

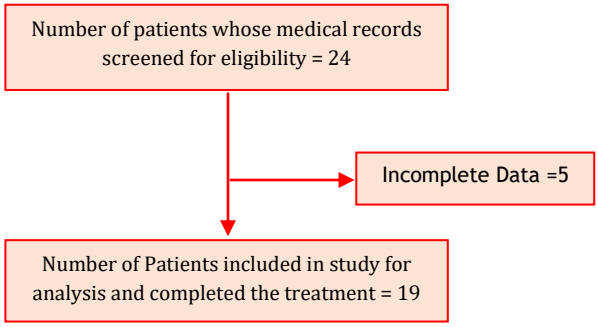


Table 3. Demographic characteristic of the study subjects (n=19)

Variable	N=19
Age	59.26 ± 8.03
Gender n (%)	
Male	15 (78.9)
Female	4 (21.1)
Past medical history n (%)	
Hypothyroidism	1 (5.26)
Obesity	3 (15.79)
Anxiety	1 (5.26)
CAD	7 (36.84)
MI	1 (5.26)
BPH	1 (5.26)

CAD, Coronary artery disease; MI, Myocardial infarction; BPH, Benign prostatic hyperplasia

Comparison of the baseline Duke Treadmill score and that after 90 days of therapy is shown in Table 4. The number of subjects having moderate (42.1 %) and high (47.4 %) risk of developing cardiovascular events at baseline were significantly decreased at day 90. There was an increase in the number of patients having low (42.1 %) and moderate (57.9%) risk after 90th day of therapy. Overall, after 90th day, no cases of high risk were reported. Figure 2 gives a graphical representation of the Duke score.

The clinical parameters were compared between baseline and 90th day values, as shown in Table 5. The maximum amount of oxygen consumption was significantly improved after the 90th day of therapy (P <0.001) [Fig 3.1]. SBP was decreased to near-normal levels after the 90th day of therapy, but it was not statistically significant (P =0.167) [Fig. 3.2]. DBP, which was normal in the patients before the therapy was initiated, was reduced after the therapy, but this reduction was not statistically significant (P=0.186) (Fig 3.3).

Table 4. Comparison of Duke Treadmill score baseline and after 90 days of treatment (n=19)

Duke treadmill score		After 90 days			Total	p-value
		Low	Moderate	High		
Baseline (1st day)	Low	2	0	0	2 (10.5%)	0.0029
	Moderate	5	3	0	8 (42.1%)	
	High	1	8	0	9 (47.4%)	
Total		8 (42.1%)	11 (57.9%)	0	19 (100%)	

Figure 2. Comparison of Duke Treadmill Score before and after treatment

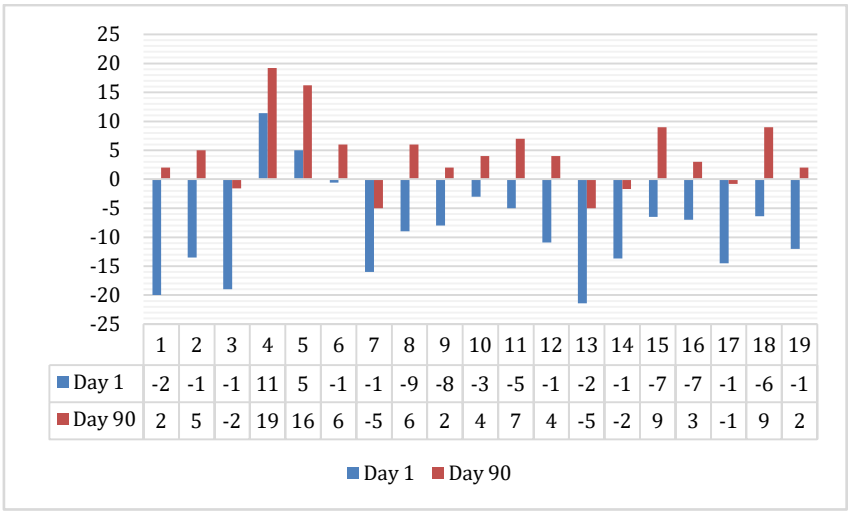
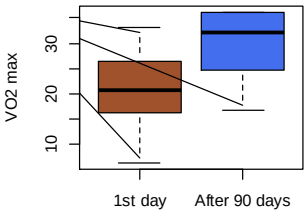


Table 5. Comparison of clinical parameters between baseline values and 90th day

Variable (n=19)	Baseline	After 90 days	Difference	p-value
VO2 max	20.74 ± 7.25	29.69 ± 6.62	-8.94	<0.001
SBP	127.68 ± 13.65	122.74 ± 11.65	4.95	0.167
DBP	78.95 ± 7.37	75.78 ± 6.92	3.16	0.186

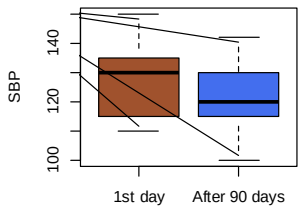
VO2 max, Maximum amount of oxygen consumption; SBP, Systolic blood pressure; DBP, Diastolic blood pressure

Figure 3. Comparison of clinical parameters between baseline and 90th day values



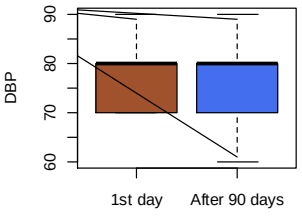
VO2 max on 1st day and after 90 days

3.1 Comparison of VO2 max



SBP on 1st day and after 90 days

3.1 Comparison of SBP



DBP on 1st day and after 90 days

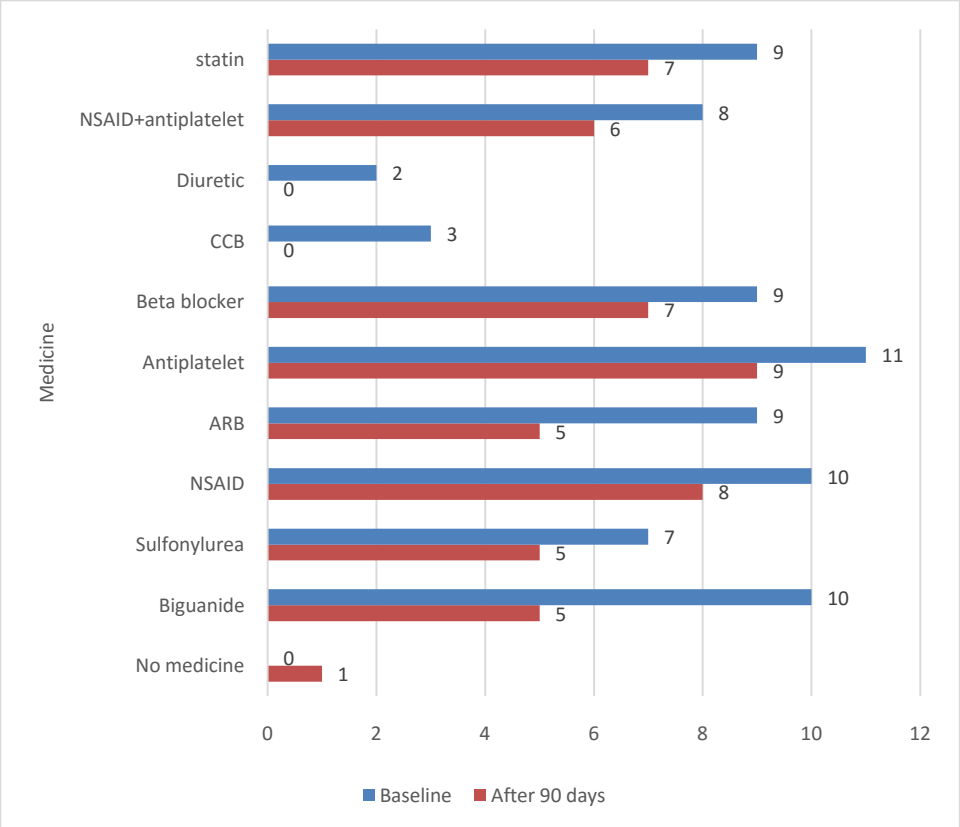
3.1 Comparison of DBP

Table 6. Consumption of allopathic medicines on day 1 and day 90 of IRP treatment

Medicine	Baseline	After 90 days
statin	9 (47.37)	7 (36.84)
NSAID+ antiplatelet	8 (42.11)	6 (31.58)
Diuretic	2 (10.53)	0 (0)
CCB	3 (15.79)	0 (0)
Beta blocker	9 (47.37)	7 (36.84)
Antiplatelet	11 (57.89)	9 (47.37)
ARB	9 (47.37)	5 (26.32)
NSAID	10 (52.63)	8 (42.11)
Sulfonylurea	7 (36.84)	5 (26.32)
Biguanide	10 (52.63)	5 (26.32)
No medicine	0 (0)	1 (5.26)

CCB, Calcium channel blockers; ARB, Angiotensin II receptor blockers; NSAID, Nonsteroidal anti-inflammatory drugs

Figure 4. Comparison of Consumption of allopathic medicines on day 1 and day 90 of IRP treatment



The consumption of allopathic medicines on day 1 and after the 90th day of therapy is tabulated in table 6. Most of the enrolled IHD subjects were on treatment of antiplatelet agents (57.89%), NSAIDs (52.63 %), beta blockers, statin and angiotensin II receptor blockers(47.37%) each. The number of subjects on allopathic medicines decreased after 90th day, as compared to the number on day 1. An illustration is given in Figure 4.

Coronary heart disease (CHD), also known as ischemic heart disease (IHD), is considered as one of the most important cause of cardiovascular mortality. Despite the presence of multiple pharmacological agents for managing IHD, there is still a growth in the prevalence of the lethal disease. HTN is known to be an important risk factor for IHD, and it is advised that IHD patients should have their BP in the normal range for better prognosis[8]. Hence, the growing prevalence of HTN is also a major contributing factor for increasing IHD cases. It is important to find novel treatment options for IHD which led us towards Ayurveda. Physicians practicing Ayurveda are using Panchakarma and allied treatment modalities for patients suffering from acute as well as chronic diseases. Hence, it was thought of testing IRP, a

novel Panchakarma technique advocated by Ayurvedic physicians for treatment of IHD, to create evidence for the same.

The Duke Treadmill was assessed to test to evaluate the effect of the IRP in patients with IHD. It was found that at baseline, 47.4% of the patients in our study were at high of cardiovascular events by the Duke score. However, at day 90 of the IRP, none of the patients were at high risk. Only 10.5% of patients were at low risk by Duke score on day 1, which increased to 42.1% after day 90 of IRP, indicating the positive response of the novel treatment modality. The Duke treadmill test has been commonly used by cardiologists worldwide for risk stratification which helps in predicting the outcome in patients suffering from CHD[9, 10]. Hence, this test was picked up as the primary variable to assess the efficacy of the IRP in IHD patients.

Functional capacity, measured by assessing the VO_2 max, is an indicator of the cardio respiratory function of an individual. A compromised VO_2 max is noted in patients suffering from cardiovascular distress, as in IHD, and the extent of decrease indicates the severity of the disease[6]. In this study, the VO_2 max was found to be significantly improved at the end of 90 days compared to the baseline, thereby indicating a betterment in the exercise capacity of the patient. The SBP and the DBP were also reduced by IRP, though the reduction in both were not statistically significant ($p>0.05$). The SBP has been found to have a correlation with aortic stiffness and endothelial dysfunction[11]. Hence, a reduced SBP may be sign of an alleviation of endothelial dysfunction.

The dependency of IHD patients on the conventional allopathic medications elevates the cost of treatment, which is an important issue in a developing country like India. Nevertheless, the exposure of patients to adverse effects of these drugs cannot be ignored. Keeping this in mind, the effect of IRP was assessed on the consumption of allopathic medicines by the patients. It was found that there was a decrease in the patients on allopathic medicines of different classes. Also, one of the patients was completely off the conventional medicines at the end of 90 days.

Cardiac ischemia occurs because of an imbalance between the myocardial demand and supply of oxygen. An increase in the coronary blood flow is the only viable option to meet this demand. If the coronary vessels are under spasm, or if these vessels have some endothelial dysfunction, then this will limit the myocardial blood flow[12]. Artery stiffness is an independent factor which can lead to coronary events. Considering the positive results of the IRP in IHD patients, it can be hypothesized that *Snehana* may be decreasing the sympathetic activity, thereby leading to decrease in the vascular tone. *Swedana* induces sweating, which may lead to peripheral vasodilation and hence, a reduction in the systemic vascular resistance. This will lead to a decrease in the afterload, thereby decreasing the cardiac workload and hence, myocardial oxygen demand. A rise of body temperature due to passive heating significantly elevates the cutaneous vascular conductance following which there is an equivalent increase in systemic conductance. A barometric homeostasis is, thus, maintained[13]. Per rectal drug administration has been associated with a reduction in the oxidative stress, which may help in reducing the myocardial ischemic damage[14]. A study comparative stated that lower part of the gastrointestinal tract is rich with parasympathetic nerves which on stimulation with per rectal drug administration (either by chemical or mechanical receptor) may cause a reduction in secretion of renin-angiotensin-aldosterone complex and may also activate the depressor area of vasomotor center which leads to vasodilatation and decrease in BP[15].

IHD is imbalance of supply versus demand of oxygen to myocardium. Endothelial dysfunction leads to atherosclerotic changes which lead to restricted coronary vasodilation due to low nitric oxide secretion. Decoction of *Tribulus territris* with *curcumin longa* and *Emblica officinalis* may have helped to reduce this endothelial dysfunction and thus, improved coronary vasodilatory reserve which might have reduced myocardial ischemia (Table 7).

This study was an observational retrospective study and thus, prospective studies can be conducted in the future to evaluate IRP in IHD patients to produce stronger evidence. The sample size was small in this study and the period of follow-up was also short. Studies with a bigger sample size and long-term follow-up in IHD patients can indicate the long-term implications of this capable treatment modality.

Table 7. Animal Studies

Herb	Action	Reference
Tribulus territris	Nitric oxide synthesizing and vasodilator	https://www.sciencedirect.com/science/article/pii/S0378874105006562
Curcumin longa	Anti-inflammatory	https://www.ncbi.nlm.nih.gov/pubmed/19594223
Emblica officinalis	Anti-Oxidant	https://www.sciencedirect.com/science/article/pii/S0378874105006057

4. CONCLUSION

Treatment with IRP is associated with an improvement in the Duke Treadmill score, thereby decreasing the risk of cardiovascular events. IRP also improves the VO2 max, thereby leading to betterment in the cardiorespiratory function. There

was a decrease in the BP by IRP, though it was not statistically significant. Future studies need to be conducted to create more evidence to support the use of the IRP in patients with IHD.

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CONFLICTS OF INTEREST None

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