ORIGINAL RESEARCH PAPER

Ayurveda

# EFFECT OF ISCHEMIA REVERSAL PROGRAM AN AYURVEDA BASED INTERVENTION ASSESSED BY CARDIAC STRESS TESTING IN KNOWN CASES OF ISCHEMIC HEART DISEASE.

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

| | |
|---|---|
| **Dr. Rohit Sane** | Managing director, MD, Madhavbaug Cardiac Hospitals and Clinics, India. |
| **Dr. Pramod Manohar** | Intensivist Head of Madhavbaug Khopoli Cardiac Hospital, Thane, Maharashtra, India |
| **Dr. Rahul Mandole*** | Head of Department of Research & Development, Madhavbaug Cardiac Clinic and Hospital, Thane, Maharashtra, India. *Corresoponding Author |
| **Dr. Gurudatta Amin** | Chief Medical Officer, Madhavbaug Cardiac Clinic and Hospital, Thane, Maharashtra, India. |
| **Dr. Pravin Ghadigaokar** | Head Medical Operations, Madhavbaug Cardiac Clinic and Hospital, Thane, Maharashtra, India. |

**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 Vidarbha region, 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 North 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 52 patients of IHD were analyzed. At the end of IRP therapy there was statistically significant reduction in weight, BMI, SBP, and DBP, VO2 peak ($p<0.001$). DTS improved from -3.11±6.36 at baseline to 3.41±7.21 at week 12 of IRP therapy and the difference was highly statistically significant ($p<0.0001$). MET at baseline was 4.99±1.88 mL/kg/min which increased to 7.82±1.96 mL/kg/min after 12 weeks of IRP therapy and the difference was highly statistically significant. **CONCLUSION:** Findings of present study suggest that IRP can serve as effective therapeutic option for the management of ischemic heart disease.

## INTRODUCTION:

In the last few decades, there has been a rapid shift in the burden of disease in India. The burden of communicable and non-communicable diseases (NCDs) is expected to be pushed back[1] by 2020 from the current situation since 1990.[2,3] In 2000, an estimated 29.8 million people (~ 3% of the total population of the subcontinent) were diagnosed with Coronary heart disease (CHD) in India.[3] This increase is aimed at changing the lifestyle of paradise, including changes in the patient's dietary pattern and the severity associated with continued economic growth and urbanization. South Asian and Asian migrants are at an unusually high risk of developing coronary artery disease (CAD).[4]

Heart disease (CVD) affects more Indians than their counterparts in developed countries, and in many other developing countries. In addition to high mortality rates, CVD is seen in Indian patients at an early age (about 10 years earlier) on average compared to other countries in the world.[5,6] This places an additional burden on the country's economy and calls for the development of effective and cost-effective treatments.

Although drugs and surgery are the standard treatment for heart disease, the Indian treatment, or Ayurveda, is effective and economical, and is now widely accepted around the world. In fact, large numbers of people are finding relief from various ailments with the help of Ayurvedic medicine. In ancient Ayurvedic texts, a variety of therapies have been suggested, which can be used to improve performance and quality of life (QOL) in patients with CVD.[7]

However, not many studies have reported the effectiveness of therapeutic compounds for improving QOL in patients with CHF. The current study evaluates the effectiveness of the ischemia transplant program (IRP), which includes a combination of Snehana (oleation), Sweden (fomentation) and Basti (drug-based enema) to improve efficiency and quality of life in patients with ischemic heart disease (IHD).

## 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) in North 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. 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]

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).[7]

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:[8]

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 below:[8]

- Mild risk- DTS ≥5, no need for coronary angiography, 4-year survival rate of 99%.
- Moderate risk: DTS +4 to -10, may require coronary angiography.
- Severe risk: DTS ≤10, definite need for coronary angiography, 4- year survival rate of 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.[9]

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.[10]

**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.

We also calculated the correlation between BMI and VO2 peak at baseline and at 12 weeks of IRP therapy.

Patient record data selection for the present study is depicted in figure 1.

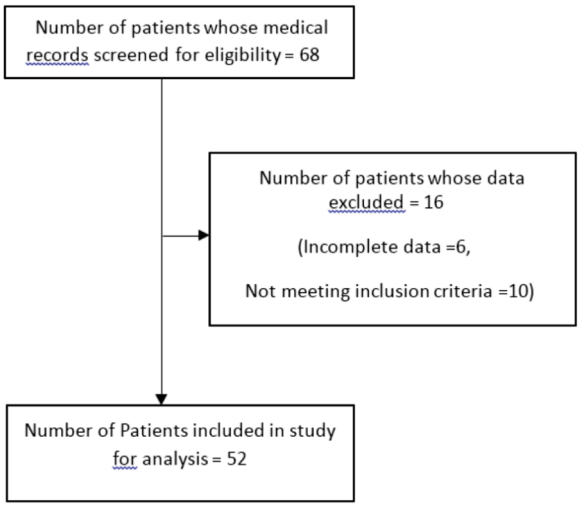


**Figure 1: Patient Record Selection For The Present Study.**

**Results:**

In the present study, medical records of 52 patients of IHD were analyzed. Mean age in the present study was 60.23 ± 11.42 years. Out of these, 29 were male (56%) and 23 were females (44%). Thus, male: female ratio was 1.26 (table 2).

**Table 2: Baseline Characteristics Of The Study Subjects (n= 52)**

| Variable | N = 52 |
|---|---|
| Age (years) | 60.23 ± 11.42 |
| Gender | |
| Male | 29 (56%) |
| Female | 23 (44%) |

*Data was expressed in % and mean ± SD*

At the end of IRP therapy there was statistically significant reduction in weight as compared (64.27±10.29 kg) to baseline (68.13±11.22 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. 25.75±5.47 mL/kg/min as compared to baseline i.e. 16.34±4.92 mL/kg/min and the difference was highly statistically significant (p<0.001). DTS improved from -3.11±6.36 at baseline to 3.41±7.21 at week 12 of IRP therapy and the difference was highly statistically significant (p<0.0001).

MET at baseline was 4.99±1.88 mL/kg/min which increased to 7.82±1.96 mL/kg/min after 12 weeks of IRP therapy and the difference was highly statistically significant [table 3].

**Table 3: Summary Of Mean Change Observed From Baseline After 12 Weeks For Different Parameters**

| Parameter | Baseline | After 12 weeks | p-value |
|---|---|---|---|
| Weight | 68.13±11.22 kg | 64.27±10.29 kg | 0.01 |
| Body Mass Index | 26.54±5.81 kg/m$^2$ | 23.49±5.20 kg/m$^2$ | 0.04 |
| Systolic Blood Pressure | 131.62±18.61 mmHg | 121.92±16.79 mmHg | 0.01 |
| Diastolic Blood Pressure | 79.61±10.51 mmHg | 72.92±9.11 mmHg | 0.01 |
| VO2 Max | 16.34±4.92 mL/kg/min | 25.75±5.47 mL/kg/min | <0.001 |
| Metabolic equivalent of task (MET) | 4.99±1.88 mL/kg/min | 7.82±1.96 mL/kg/min | <0.001 |
| Duke Treadmill Score (DTS) | -3.11±6.36 | 3.41±7.21 | <0.0001 |

On analyzing the angina index, it was found that mean angina index was 1.39 at baseline and it reduced to 0.32 at week 12 of IRP (p<0.001) [figure 2].

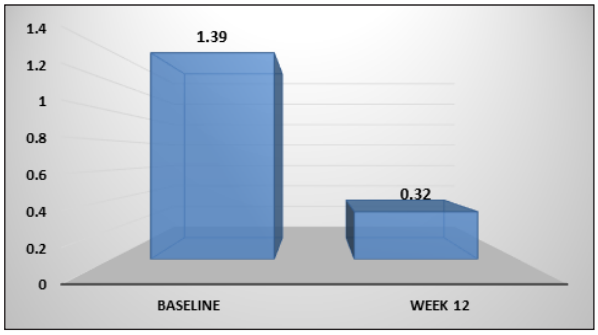


**Figure 2: Mean Angina Index In Patients Of The Ihd In The Present Study.**

On analyzing the DTS, number of patients in low risk category increased from 12 (29%) at baseline to 26 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 4].

**Table 4: Duke's Trade Mill Score In Patients Of Ihd In The Present Study.**

| Timeline | Duke's treadmill score (DTS) [n=41] | | | |
|---|---|---|---|---|
| | Low risk (≥5) | Moderate risk (-10 to 4) | Severe risk (≤ -11) | p-value |
| Baseline | 12 (29%) | 24 (58%) | 5 (13%) | <0.001 |
| Week 12 | 26 (63%) | 13 (32%) | 2 (5%) | |

Ability to perform strenuous activity was evaluated on the basis of MET usage. At baseline 12 (29%), 24 (58%), and 5 patients (12%) were able to perform light, moderate and vigorous exercise, respectively. After 12 weeks of IRP therapy 1 (2%), 12 (29%), and 28 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 5].

**Table 5: Table Indicating Shift In The Metabolic Equivalent Of Task Over Time**

| Timeline | Metabolic equivalent of task (MET) [n=41] | | | |
|---|---|---|---|---|
| | Light exercise (< 3.0 METS) | Moderate exercise (3 to 6 METS) | Vigorous exercise (> 6 METS) | p-value |
| Baseline | 12 (29%) | 24 (58%) | 5 (12%) | <0.001 |
| Week 12 | 1 (2%) | 12 (29%) | 28 (69%) | |

On analyzing the correlation between BMI and Vo2 max, it was found that there was negative correlation between the two parameters at baseline (r = -0.11) and at week 12 (r = -0.35) [figure 3].

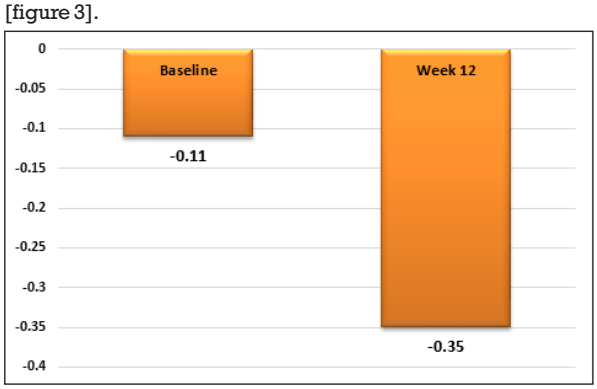


**Figure 3: Correlation Between Bmi And Vo2 Max.**

On analyzing the dependency on conventional drugs, it was found that overall the consumption of all drug categories was reduced after IRP therapy. 4 (7%) patients were not taking medications at baseline which increased to 16 patients (31%) after 12 weeks of IRP therapy (table 6).

**Table 6: Consumption Of Allopathic Medication At Baseline And Post 12 Weeks**

| Medication | Baseline n(%) | After 12 weeks n(%) |
|---|---|---|
| Angiotensin II receptor blockers | 9 (17%) | 3 (6%) |
| β-blocker | 5 (9.6%) | 2 (4%) |
| Diuretics | 1 (2%) | 1 (2%) |
| $Ca^{2+}$ channel blockers | 3 (6%) | 2 (4%) |
| NSAIDs | 6 (11.7%) | 3 (6%) |
| Biguanides | 21 (40.3%) | 12 (23%) |
| DPP4 | 12 (23%) | 6 (11.7%) |
| Sulfonylureas | 18 (34.6%) | 10 (19%) |
| Insulin | 14 (27%) | 7 (13.4%) |
| Antiplatelets | 10 (19%) | 5 (9.6%) |
| Statins | 9 (17.3%) | 5 (9.6%) |
| Nitrates | 7 (13.4%) | 2 (4%) |
| No medication | 4 (7%) | 16 (31%) |

**Discussion:**

The last ten years have seen the discovery of the novel anti-ischemic drugs and new emergence understanding of the pathophysiology of this disease. In addition, IHD continues to be one of the leading providers of global disease as well death rates. Therefore, it should be wise to do so check out new treatment options with high efficiency and a few security issues. Ayurveda is another powerful and practical alternative to conventional medicine in the management of IHD.[7]

In the present study, we included three ayurvedic processes in our evolution of IRP i.e. Snehana, Sweden and. Snehana is an important Poorvakarma which results in anxiety and thus reduces the is sensitive to the activity associated with IHD.[11] Swedana prepares for the essentials measure of obesity management.[11] It drinks the ripe Dosha spread physically and thus help in weight loss obesity.[11] Despite this; improves Sodium and fluid retention thus reduces preload and oxygen demand for IHD cards patients.[12,13] In Basti, a minor cleanup took place which help to reduce sodium retention and thus we control BP as evidenced by a previous study.[14] Basti, Gokshur, haridra and Aamalki benefits from IHD with promoting lead nitric oxide synthesis vasodilation and subsequent reduction in upload first. Apart from this, haridra and amalki has anti-inflammatory and antioxidant properties properties.[15]

Last point on our study was VO2 peak. Exercise tolerance it creates one of the most outstanding symbols of IHD. VO2 height is maximum oxygen that can be used during exercise. IHD the patient has a problem with diastolic dysfunction, which is why the high value of VO2 decreases in such cases there shows in the clinic as a decrease in exercise / activity capacity.[16] Duke's treadmill is used as diagnostic and forensic investigations are at risk IHD patients.[16] In our study, both VO2 Duke high scores and treadmill points are important (high statistical value) improved. Research shows that the development of Duke's school and a higher VO2 value is associated with better prediction in IHD patients.[16,17,18] Therefore, significant reductions in VO2 peak and Duke's the points behind the IRP in our study show good prediction for heart failure sickness and death.

It is important to note that Beaver W. et al. studied oxygen capture and cardiac breathing working for normal and obese people too reported that obese subjects have low VO2max there are ordinary people.[19] There were several similar studies in which it has been shown to be dependent athletes have a recurring value of VO2 max as compared to obese people with aerobic effects training and age of respiratory strength be studied.[20-22] Also, in the relationship study between high aerobic strength and heart disease hazardous

substances, was reported to be high aerobic energy has a recurring relationship with BMI.[23] In our study negative correlation was found between BMI and Vo2 max. Similar trends were noted in other clinical studies wherein reduction in BMI with therapy and other interventions there was greater improvement in VO2 max values.[24,25]

Thus, overall the significant improvement in DTS, SBP, DBP, VO2 max, BMI, METs is a welcome sign with the use of IRP in management of IHD. But the present study had certain limitations. Due to its retrospective design, the chances of bias cannot be rules out. It is recommended that prospective studies with large sample size should be done in future to compare and validate the results of the present study.

## CONCLUSION:

In the present study, IRP was able to induce significant improvement in all parameters like Body mass index, systolic and diastolic blood pressure, VO2 peak, Dukes treadmill score, as well as it increased number of patients who could perform vigorous activities after the therapy, reduced dependency on conventional medications, and increased patient compliance. Moreover IRP lead to increased negative correlation between BMI and VO2 peak which is welcome sign in patients of myocardial ischemia. Thus, IRP can serve as potent therapeutic alternative in management of ischemic heart disease.

**Conflicts Of Interest:** None declared by the authors.

**Source Of Funding:** Not applicable.

## REFERENCES:

1. World Health Organization. Global Status Report on Non-Communicable Diseases 2014. Geneva, Switzerland: World Health Organization; 2014.
2. Fuster V, Kelly B. Board for Global Health. Promoting Cardiovascular Health in Developing World: A Critical Challenge to Achieve Global Health. Washington, DC: Institutes of Medicine; 2010.
3. Gaziano T, Gaziano J. Epidemiology of cardiovascular disease. In: Harrison's Principles of Internal Medicine. 19th ed. New York, NY: McGraw Hill; 2016;266.e1e5.
4. Gupta R, Guptha S, Sharma K, et al. Regional variations in cardiovascular risk factors in India: India Heart Watch. World J Cardiol 2012;4:112e20.
5. Forouzanfar M, Moran A, Flaxman A, et al. Assessing the global burden of ischemic heart disease, part 2: analytic methods and estimates of the global epidemiology of ischemic heart disease in 2010. Global Heart 2012;7:331e42.
6. Global Burden of Diseases 2013 Mortality and Causes of Death Collaborators. Global, regional, and national levels of age-sex specific all-cause and cause-specific mortality for 240 causes of death, 1990-2013: a systematic analysis for the Global Burden of Disease Study 2013. Lancet 2015;385:117e71.
7. Sane R, Gond B, Raje G, et al. Evaluation of the efficacy of Ischemia Reversal Program (IRP) in patients suffering from Ischemic Heart Disease (IHD) with known history of Hypertension: A Retrospective Study. J Ayu Med Sci 2018;3(2):377-83.
8. Lairikyengbam S, Davies A. Interpreting exercise treadmill tests needs scoring system. BMJ. 2002; 325(7361): 443.
9. Buttar K, Saboo N, Kacker S. A review: Maximal oxygen uptake (VO2 max) and its estimation methods. International Journal of Physical Education, Sports and Health 2019; 6(6): 24-32.
10. Jetté M, Sidney K, Blümchen G. Metabolic equivalents (METS) in exercise testing, exercise prescription, and evaluation of functional capacity. Clin Cardiol 1990; 13(8):555-65.
11. Gui Q, Xu Z, Xu K, et al. The efficacy of ginseng-related therapies in type 2 diabetes mellitus: an updated systematic review and metaanalysis. Medicine (Baltimore) 2016;95:e2584.
12. Huang H, Lai S, Wan Q, et al. Astragaloside IV protects cardiomyocytes fromanoxia/reoxygenation injuryby upregulatingthe expressionofHes1 protein. Can J Physiol Pharmacol 2016;94:542–53.
13. Fleming J, Kris-Etherton P. The evidence for a-linolenic acid and cardiovascular disease benefits: comparisons with eicosapentaenoic acid and docosahexaenoic acid. Adv Nutr 2014;5: 863S–76S.
14. Choudhary K, Sharma P, Sharma V. Hypertension and its management through Panchakarma, J of Ayurveda and Hol Med. 2015;3(3):28-31.
15. Uebaba K, Xu FH, Ogawa H, et al. Psychoneuroimmunologic effects of ayurvedic oil dripping treatment. J Altern Complement Med. 2008;14:1189–1198.
16. Taghadosi M, Arani Z, Gilani H. Quality of life in patients with ischemic heart disease. Journal of Nursing and Midwifery Sciences 2014: 1(1): 19-26
17. Sane R, Aklujkar A, Patil A, Mandole R. Effect of heart failure reversal treatment as add-on therapy in patients with chronic heart failure: A randomized, open-label study. Indian Heart Journal. 2017;69(3):299-304.
18. Liperoti R, Vetrano D, Bernebei R, etal. Herbal medications in cardiovascular medicine. J Am Coll Cardiol 2017;69:1188–99
19. Beaver W, Wasserman K, Whipp B. Improved detection of lactate threshold during exercise using a log-log transformation. J Appl Physiol 1985; 59(6):1936-40.
20. Skinner J, Wilmor K, Krasnoff J. Adaptation to a standardized training program and changes in fitness in a large, heterogeneous population: the heritage Family Study. Med Sci Sports Exerc 2000; 32(1):157-161.
21. Walter G, Vandenborne K, McCully K, et al. Noninvasive measurement of phosphocreatine recovery kinetics in single human muscles. Am J Physiol 1997; 272(2):525-534.
22. Jones A, Poole D. Oxygen Uptake Kinetics in Sport, Exercise and Medicine. J Sports Sci Med. 2005; 4(1):84.
23. Lokandaivelu K, Leiden B, O' Gara P et al. Non-adherence to cardiovascular medications. European Heart Journal 2014; 35: 3267–3276.
24. Dhara S, Chatterjee K. A Study of VO2 max in Relation with Body Mass Index (BMI) of Physical Education Students. Res J Physical Education Sci 2015; 3(6):9-12.
25. Pandey K, Singh V, Upadhyay A, et al. Effect of BMI on maximum oxygen uptake of high risk individuals in a population of eastern Uttar Pradesh. Ind J Comm Health. 2014; 26(1):20-24.