Original Research Article

Understanding the Role of Ayurveda Based Ischemia Reversal Program and Low Carbohydrate Diet in Reduction of Risk of Heart Disease.

ABSTRACT

Background: Cardiovascular disease is a global epidemic which is commonly associated with obesity. Maximum aerobic capacity (VO2peak) and Duke treadmill score (DTS) are associated with prediction of risk of heart disease so any positive modification in these factors can prevent risk of heart disease. The present study was conducted to understand the role of low carbohydrate diet and Ayurveda based IRP in management of IHD with obesity.

Material and Methods: A retrospective observational study was conducted in Madhavbaug Hospital in April 2017. All patients with clinical evidence of IHD and BMI > 30 kg/m2 were included in the study. During the study period of 90 (±15) days, the patients received seven sessions of IRP which included a combination of Snehana / external oleation or massage, Swedana / passive heat therapy and Basti kadha. Simultaneously, patients were prescribed supervised low carbohydrate diet daily for 90 days. The primary efficacy end point was improvement in VO2 peak after 90 day therapy while secondary end points include reduction in reduction in Duke treadmill score, BMI, body weight, SBP, DBP after 90-day follow-up as compared to day 1 (baseline).

Results: A total of 50 patients were enrolled and after screening 37 were included in the study. Most of the enrolled patients were middle aged (53.22 ± 10.78 years) and female sex (59.45%). The primary end-point used in the present study (VO2 peak) increased significantly from 17.82 ± 7.23 on Day 1 to 26.65 ± 6.14.at day 90 (p<0.001). Such significant changes were also appreciable in the Duke treadmill score, BMI, SBP, DBP values measured on day 1 and day 90 respectively (p<0.001 for all). This was associated with an appreciable decrease in the concomitant allopathic medications used by the patients.

Conclusion: The present study revealed that treatment with low carbohydrate diet and ischemia reversal program caused significant improvement in VO2 peak, Duke's treadmill score along with BMI, SBP, DBP of patients suffering from IHD with obesity. This suggests IRP with LCD can be beneficial in reducing risk of heart disease in known IHD patients.

1. INTRODUCTION

The epidemic of cardiovascular disease (CVD) is a global phenomenon that showed increased incidence in both developed and developing nations [1]. As per the Registrar General of India estimates, CVD contributed to 17% of total deaths and 26% of adult deaths in 2001-2003, which increased to 23% of total and 32% of adult deaths in 2010-2013. The World Health Organization (WHO) and Global Burden of Disease Study have also highlighted increasing trends in years of life lost (YLLs) and disability-adjusted life years (DALYs) from CVD in India [2]. IHD contributes maximum amongst deaths due to CVD in India (>80%) [3]. Case-control studies have reported that important risk factors for CVD include obesity amongst others [4].The higher prevalence of cardiovascular disease in obese individuals is indirectly mediated by the increased occurrence of other risk factors like hypertension, diabetes, and dyslipidemia, either individually or as part of the metabolic syndrome [4]**.** Several large prospective studies have investigated the associations between obesity and CHD

death, with meta-analysis showing a 40% increase in mortality for every 5 kg/m2 increase in body mass index (BMI) above 25 kg/m2 [5].

 The current management protocol of IHD includes long term therapy with drugs like antiplatelet agents (Aspirin/Clopidogrel), beta blockers, ACE inhibitors which reduce cardiac workload, statins to correct dyslipidemia [6]. However, long term use of these drugs have doubtful efficacy with serious safety concerns [6]. Hence, the search for safe and effective alternative is of utmost importance.in the management of IHD. Ayurveda is an age old scientific medicinal system indigenous to India. Ayurveda means 'knowledge of life', which comprises of two Sanskrit words, Ayu (Life) and Veda (Knowledge or Science). The principal aim of Ayurveda is to achieve equilibrium between the physiological and structural entities, which ultimately culminates in good health. Any disparity or unevenness because of external or internal factors may lead to disease development [7]. Ayurvedic treatment aims to restore the equilibrium through the utilization of different techniques, regimens, diet as well as medicines [8].

In our institute (Madhavbaug Clinics and Hospital) the Ayurvedic physicians are using a multi-faceted obesity management protocol to treat IHD with obesity, which includes a low-carbohydrate diet and combination of herbal treatment namely Snehana, Swedana, Basti kadha. However, a literature search revealed that there is a dearth of published literature to demonstrate the efficacy of this treatment modality in obese patients. In this backdrop, the present study was conducted to demonstrate the efficacy of low carbohydrate diet and ischemia reversal program in treating IHD with obesity.

2. MATERIALS AND METHODS

Study setting and patient selection: A retrospective observational study was conducted in Madhavbaug Clinics from all over Maharashtra, for a period of 3 -months starting from April 2017 to April 2018 to address the study objective. All patients with clinical evidence of IHD and BMI ≥ 30 KG/m^2 were considered eligible to participate in the study. Patients were recruited after obtaining written informed consent from them .The study was conducted according to the ethical principles mentioned in the Declaration of Helsinki, Good Clinical Practices, and applicable regulatory requirements.

Study procedure: Patients with clinical evidence of IHD and BMI>30% were considered to be eligible in the 90 day study after initial screening. The exclusion criteria were (i) Severe hepatic or renal disease (ii) Uncontrolled diabetes (iii) Pregnancy. On day 1 of study, baseline clinical status of the patient was determined by measuring Duke's treadmill score, VO2peak, BMI, SBP, and DBP as per international criteria. Following this, low carbohydrate diet plan and ischemia reversal program (IRP) was started on the patient. A supervised daily diet plan with calorific value 800 kcal was prescribed for the patient which consisted of 35% carbohydrate: 25% protein:40% fat. The patient was asked to follow the diet plan for 90 days. In the study period of 90 (±15) days, the patient also received seven sessions of IRP details of which are given below. The IRP is a combination of Panchakarma and allied therapies. IRP uses various decoctions and oils and constitutes of a 3-step procedure namely:

a. Snehana / External oleation or massage (25-30 minutes): Massage or external oleation (centripetal upper strokes on the body).

b. Swedana / Passive heat therapy (15 -20 minutes): Dashmoola (group of ten herbs) steam of temperature not more than 40 was then passed steadily for 10-15 minutes. After the treatment, patients were asked to relax for 3-4 minutes.

c. Basti kadha: Drug administered per-rectal, should be in body for > 15 minutes for maximum absorption.

At the end of 90 days, the patients were examined and Duke treadmill score, VO2peak, BMI, SBP, DBP were again measured and compared with the baseline.

73   The detailed schedule of Ayurvedic ischemic reversal program is described below in Table 1.

74   **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 $\leq$ 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

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77   ***2.1 Statistical analysis****:* Data was entered in MS excel and analyzed using R Version 3.5.1
78   software. The data of only those patients who could complete the entire treatment of 90 days were
79   considered for analysis. The primary efficacy end point was Improvement in VO2 peak after 90-days
80   therapy while secondary end points include reduction in reduction in Duke treadmill score, BMI, body
81   weight, SBP, DBP after 90-day follow-up as compared to day 1 (baseline). Paired T test were used to
82   test statistical significance for primary and secondary end points. We also calculated Correlation
83   between weight & BMI and VO2 peak.

84   **3. RESULTS:**

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86   During the study period, a total of 50 patients were enrolled and after screening 37 were included in
87   the study. All of them continued the treatment up to day 90 and were considered for analysis. There
88   were no reports of serious adverse event in the study participants. Most of the enrolled patients were
89   middle aged (53.22 ± 10.78) years and female sex (59.45%). The baseline VO2 peak, Duke Score,
90   BMI, SBP, DBP were measured on Day 1 and has been mentioned in Table 2. IHD with obesity is
91   related to several chronic diseases like hypertension, dyslipidemia and diabetes mellitus and hence
92   these patients are prescribed medicines for these co-morbidities. In our study, the concomitant
93   medications consumed by the patients on day 1 include beta blocker, ARB, diuretics, statin, NSAID,
94   anti-platelet drugs, calcium channel blockers, sulfonylurea, biguanide and thiazolidinedione. However,
95   at the end of day 90, there was an appreciable decrease in the medication use by the patients which
96   has been shown in table 3, figure 2. The primary end-point used in the present study (VO2 peak)
97   increased significantly from 17.82 ± 7.23 on Day 1 to 26.65 ± 6.14.at day 90 (p<0.001). Such
98   significant changes were also appreciable in the Duke treadmill score, BMI, SBP, DBP values
99   measured on day 1 and day 90 respectively (p<0.001 for all) details of which is shown in table no 2,
100   figure 1. We also explored the association between VO2 peak value and BMI at day 1 and day 90.
101   Vo2 peak and BMI showed negative correlation both at day 1 (r =0.15) and at day 90 (r= 0.29). (Table
102   4/Figure 3)

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107 **Table 2: Comparison of clinical parameters between baseline values and 90th day**

| Variable (n=37)	Baseline (day 1)	After 90 days	Difference	*P-value*
VO2peak	17.82 ± 7.23	26.65 ± 6.14	-8.83	<0.001**
Duke Treadmill Score	-9.68 ± 5.66	1.22 ± 5.84	-10.90	<0.001***
BMI	32.96 ± 3.26	31.23 ± 3.95	1.74	<0.001*
Weight	80.44 ± 9.48	76.21 ± 10.70	4.23	<0.001**
SBP	133.24 ± 16.17	121.11± 14.88	12.14	<0.001***
DBP	84.24 ± 10.03	77.05 ± 7.23	7.19	<0.001***

108 *** *Highly significant; Duke Treadmill Score, SBP, DBP*

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111 **Figure 1: Comparison of clinical parameters between baseline (Day 1) and Day 90.**
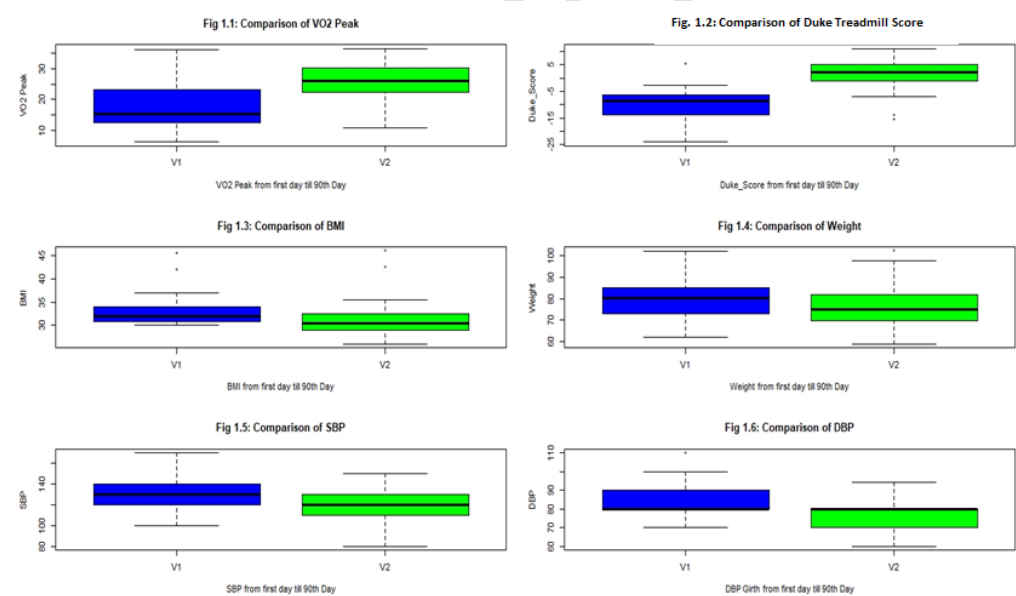
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118   **Table 3: Consumption of allopathic medicines on days 1 and 90**

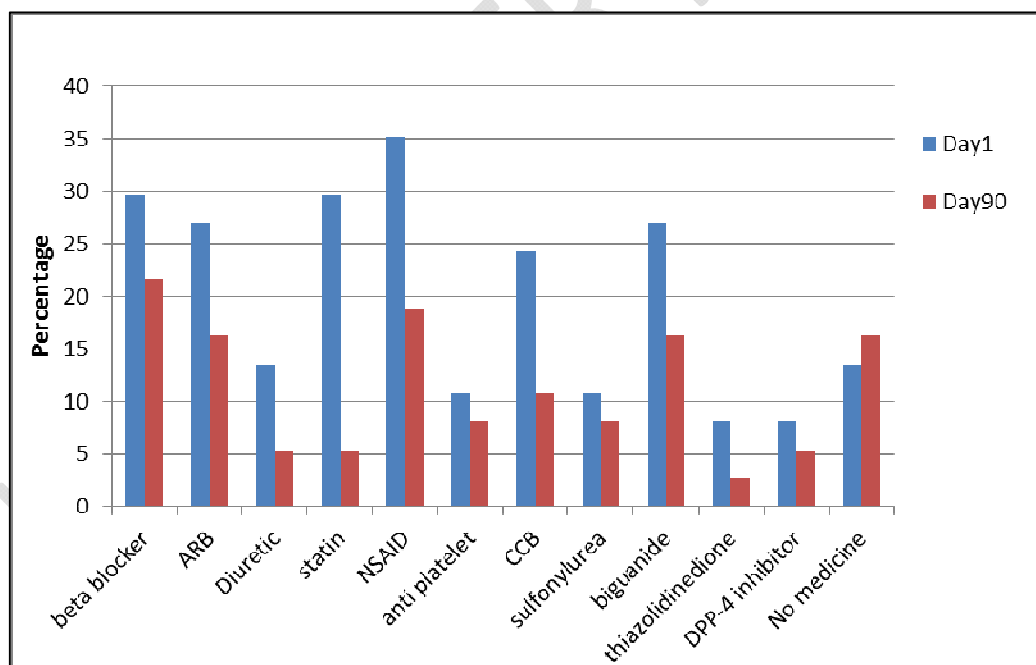| Name of medicine	Day 1	%	Day 90	%
Beta blocker	11	29.73	8	21.62
ARB	10	27.03	6	16.22
Diuretic	5	13.51	2	5.41
Statin	11	29.73	2	5.41
NSAID	13	35.14	7	18.92
Anti platelet	4	10.81	3	8.11
CCB	9	24.32	4	10.81
Sulfonylurea	4	10.81	3	8.11
Biguanide	10	27.03	6	16.22
thiazolidinedione	3	8.11	1	2.70

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123   **Figure 2: Consumption of allopathic medicines at days 1 and 90 days (N = 37)**

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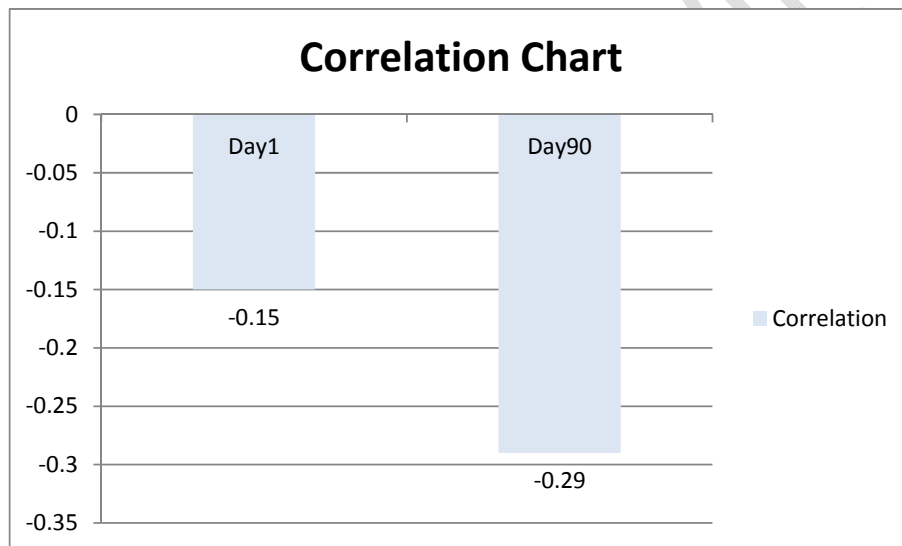Table 4: Correlation between VO2 Peak and BMI at 1st day and 90th Day

		VO2 Peak	
		Day1	Day90
BMI	Day1	-0.15	-0.2
	Day90	-0.05	-0.29

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Figure 3: Correlation Chart between VO2 Peak and BMI at day1 and day90.

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4. DISCUSSION:

The last decade witnessed discovery of novel anti-ischemic drugs and evolution of newer insights in pathophysiology of the disease. Despite that, IHD continues to be one of the leading contributors to global morbidity and mortality rates. Hence, it should be prudent to explore newer treatment options with high efficacy and few safety concerns. Ayurveda is a potent and viable alternative to standard therapy in the management of IHD with obesity. Classic ayurvedic texts have described obesity (*Medaroga*) as a causative factor for IHD (*Hridroga*). Based on classic ayurvedic texts, we combined low carbohydrate diet with certain Ayurveda procedures to treat IHD with obesity.

The traditional diet of India is rich in carbohydrates, with large quantities of rice in the coastal regions, chappatis in the interiors, and heavy consumption of bread all over [9]. The widespread availability of fried and unhealthy fast food, adds empty calories to the diet .It may be noted that as per National Sample Survey Office's (NSSO) 2011-12 data on Nutritional Intake per capita calorie consumption is 2099 kilocalories per day in rural areas and 2058 kilocalories per day in urban areas while the average metabolic rate of person with sedentary lifestyle is 1400-1500 kcals [9,10]. Hence creating a negative energy balance plays crucial role in weight loss. As per the line of treatment of obesity, the diet prescribed should be Apatarpana (no nourishing).The Apatarpana quality of food will help in the reduction of fat in the body thus reducing myocardial oxygen demand [11]. This has also been reiterated in recent studies which indicate diets lower in carbohydrate have shown promise for weight loss when compared to typical reduced energy and fat diets [12,13]. In the present study also, low carbohydrate diet helped in reducing body weight, BMI and improving VO2 peak, Duke Treadmill score.

In the present study, we have combined three ayurvedic procedures in our Ischemia reversal program namely Snehana, swedana and basti kadha. Snehana is an important Poorvakarma which has anxiolytic effect and thus reduces the sympathetic over activity associated with IHD [14].Swedana is an important preparatory measure for the management of obesity [14]. It liquefies the vitiated Dosha which are spread through the body and thus helps in reducing obesity [14]. Besides this; it ameliorates the sodium and fluid retention thus reducing the preload and myocardial oxygen demand in IHD patients [15,16]. In Basti, mild purgation occurs which help in reducing the sodium retention and thus controlling the BP as evidenced in earlier study [17]. In basti, Gokshur, haridra and Aamalki are used which offer benefit in IHD by stimulating nitric oxide synthesis which leads to vasodilation and subsequent decrease in preload. Apart from this, haridra and amalki possess anti-inflammatory and antioxidant properties [18]. The primary endpoint in our study was VO2 peak. Exercise intolerance constitutes one of the hallmark symptoms of IHD. VO2 peak measures the maximum oxygen that can be utilized during exercise. IHD patient suffers from diastolic dysfunction, hence VO2 peak is reduced in such cases which manifests clinically as reduced exercise/work capacity [19]. Duke's treadmill score is used as diagnostic and prognostic investigation in risk patients of IHD [19]. In our study, both VO2 peak and Duke's treadmill score were significant (high statistical significance) improved. Studies show that improvement in Duke's score and VO2 peak are associated with better prognosis in IHD patients [19, 20, 21]. Hence, significant reduction in VO2 peak and Duke's treadmill score after IRP in our study indicates favorable prognosis in reducing cardiovascular morbidity and mortality.

While exploring the effectiveness of the IRP in IHD, we found that it showed significant (very high statistical significance) improvement in DBP, SBP, BMI (high statistical significance) at the 90th day of the whole procedure. SBP is one of the prognostic markers for patients of IHD. Reduction in SBP is associated with better prognosis in IHD, since it reduces afterload of the ventricles and also improves endothelial health [19].

The IHD patients usually depend on conventional allopathic medication which escalates the healthcare cost many fold in a resource constraint country like India. In addition, adverse effects of these allopathic medicines lead to decreased adherence and increased morbidity. In our study, following 90 days treatment with low calorie diet and IRP, there was significant reduction in dependency on almost all the class of anti-ischemic drugs.

However, the present study is limited by the short duration of therapy (90 days) and small sample size. Further adequately powered studies with longer duration can offer more meaningful evidence on efficacy of this treatment modality.

198 **5. CONCLUSION:**
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200 The present study revealed that 90 days treatment with low carbohydrate diet and ischemia reversal
201 program caused significant improvement in VO2peak, Duke's treadmill score, BMI, SBP, DBP of
202 patients suffering from IHD with obesity. This was associated with reduction in patient's dependency
203 on allopathic medications. Thus, the IRP with low carbohydrate diet may be considered as a viable
204 alternative to standard allopathic treatment of IHD with obesity.

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