

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

**Rohit Sane¹, Amruta Wadekar², Kranti Shinde³, Heena Furia⁴,
Priyanka Upadhyay⁴ and Rahul Mandole^{1*}**

¹*Department of Research and Development, Madhavbaug Cardiac Care Clinics and Hospitals, Mumbai, India.*

²*Madhavbaug Cardiac Care Clinics and Hospitals, Pune, India.*

³*Madhavbaug Cardiac Care Clinics and Hospitals, Kolhapur, India.*

⁴*Madhavbaug Cardiac Care Clinics and Hospitals, Mumbai, India.*

Authors' contributions

This work was carried out in collaboration among all authors. Author RS designed the study, performed the statistical analysis, wrote the protocol, and wrote the first draft of the manuscript. Authors HF and PU managed the analyses of the study. Author RM managed the literature searches. All authors read and approved the final manuscript.

Article Information

Editor(s):

- (1) Dr. Farhad Ali Associate Professor, Head of Mathematics Department, City University of Science and IT Peshawar, Pakistan.
(2) Dr. Hugo R. Ramos, Adjunct Professor, Department of Internal Medicine, Hospital de Urgencias, Córdoba, Argentina.

Reviewers:

- (1) Muruganandan Shanmugam, Wayne State University, USA.
(2) Arthur N. Chuemere, University of Port Harcourt, Nigeria.
Complete Peer review History: <http://www.sdiarticle3.com/review-history/46867>

Original Research Article

Received 28 November 2018

Accepted 16 February 2019

Published 03 April 2019

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 Ischemia Reversal Program (IRP) in management of *Ischemic Heart Disease* (IHD) with obesity.

Materials and Methods: A retrospective observational study was conducted in Madhavbaug

Hospital in April 2017-2018. 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 Local Coverage Determination (LCD) can be beneficial in reducing risk of heart disease in known IHD patients.

Keywords: Ischemic heart disease; ischemia reversal program low carbohydrate diet; obesity.

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

2.1 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 2018 to address the study objective. All patients with clinical evidence of IHD and BMI ≥ 30 KG/m² 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.

2.2 Study Procedure

Patients with clinical evidence of IHD and BMI greater than 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 katha: 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.

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

2.3 Statistical Analysis

Data was entered in MS excel and analyzed using R Version 3.5.1 software. The data of only those patients who could complete the entire treatment of 90 days were considered for analysis. The primary efficacy end point was Improvement in VO₂ peak after 90-days 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). Paired T test were used to test statistical significance for primary and secondary end points. We also calculated Correlation between weight & BMI and VO₂peak.

3. RESULTS

During the study period, a total of 50 patients were enrolled and after screening 37 were included in the study. All of them continued the treatment up to day 90 and were considered for analysis. There were no reports of serious adverse event in the study participants. Most of the enrolled patients were middle aged (53.22 ± 10.78) years and female sex (59.45%). The baseline VO₂peak, Duke Score, BMI, SBP, DBP were measured on Day 1 and has been mentioned in Table 2. IHD with obesity is related to several chronic diseases like hypertension, dyslipidemia and diabetes mellitus and hence these patients are prescribed medicines for these co-morbidities. In our study, the concomitant medications consumed by the patients on day 1 include beta blocker, ARB, diuretics, statin, NSAID, anti-platelet drugs, calcium channel blockers, sulfonylurea, biguanide and thiazolidinedione. However, at the end of day 90, there was an appreciable decrease in the medication use by the patients which has been shown in Table 3, Fig. 2. The primary end-point used in the present study (VO₂peak) 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) details of which is shown in Table no 2, Fig. 1. We also explored the association between VO₂ peak value and BMI at

day 1 and day 90. Vo2 peak and BMI showed negative correlation both at day 1 ($r = 0.15$) and at day 90 ($r = 0.29$). (Table 4/Fig. 3).

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.

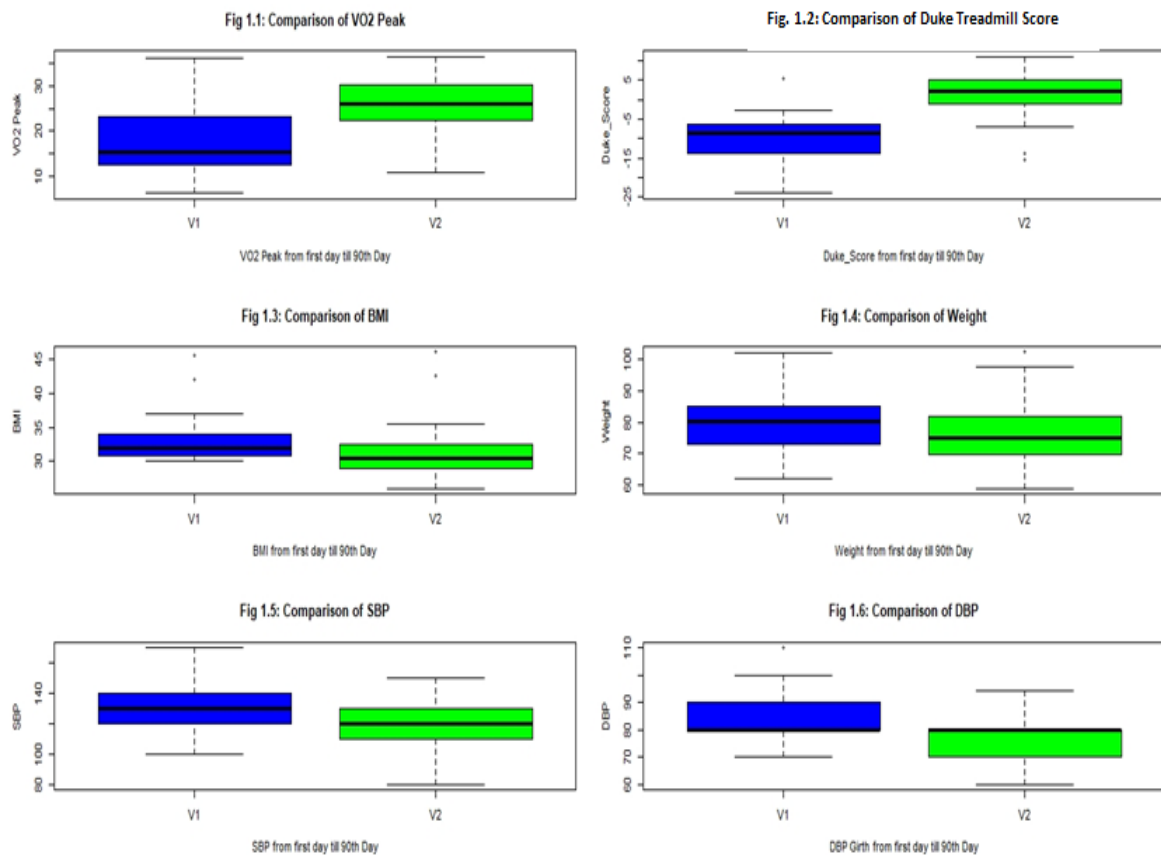


Fig. 1. Comparison of clinical parameters between baseline (day 1) and day 90

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	<i>Dashmoola</i> (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 <i>GHA</i> decoction 100 ml	15 minutes

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***

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

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

Table 4. Correlation between VO2peak and BMI at 1st day and 90th day

		VO2 Peak	
		Day 1	Day 90
BMI	Day 1	-0.15	-0.2
	Day 90	-0.05	-0.29

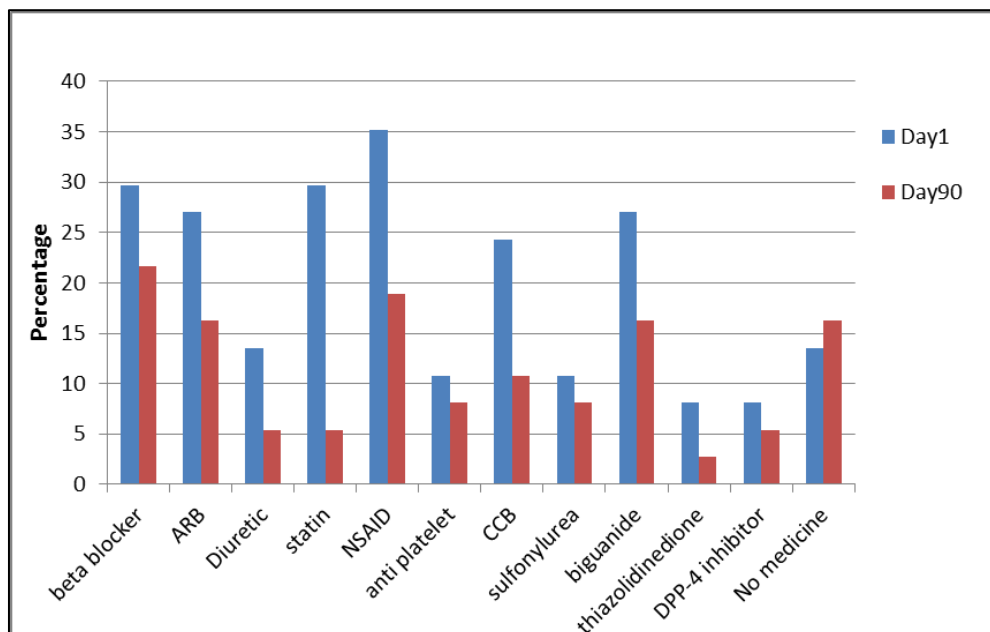


Fig. 2. Consumption of allopathic medicines at days 1 and 90 days (N = 37)

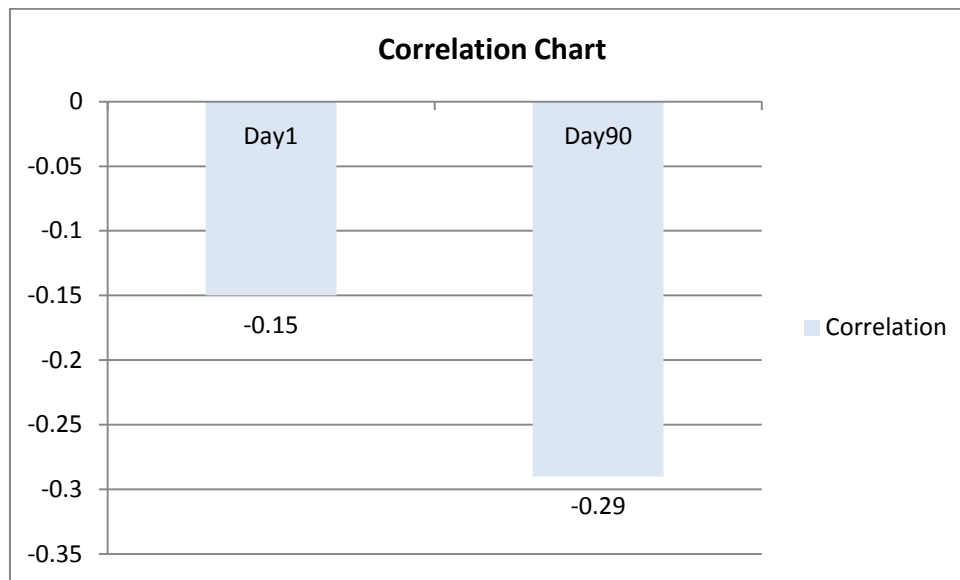


Fig. 3. Correlation chart between VO₂peak and BMI at day 1 and day 90

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.

5. CONCLUSION

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

CONSENT

Informed consent obtained from the patients.

ETHICAL APPROVAL

The study was conducted according to the ethical principles mentioned in the Declaration of Helsinki, Good Clinical Practices, and applicable regulatory requirements.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

REFERENCES

1. Gersh BJ, Sliwa K, Mayosi BM, Yusuf S. Novel therapeutic concepts: The epidemic of cardiovascular disease in the developing world: Global implications. *Eur Heart J*. 2010;31:642–648.
2. Gupta R, Mohan I, Narula J. Trends in coronary heart disease epidemiology in India. *Ann Glob Health*. 2016;82:307-15.
3. GBD Profile: India. Institute of Health Metrics and Evaluation. Available:http://www.healthdata.org/sites/default/files/files/country_profiles/GBD/ihme_gbd_country_report_india.pdf Accessed October 16, 2018.
4. Mathew B, Francis L, Kayalar A, Cone J. Obesity: Effects on cardiovascular disease and its diagnosis. *J Am Board Fam Med*. 2008;21:562–568.
5. Logue J, Murray HM, Welsh P, et al. Obesity is associated with fatal coronary heart disease independently of traditional risk factors and deprivation. *Heart*. 2011; 97:564–8.
6. Qaseem A, Fihn SD, Dallas P, Williams S, Owens DK, Shekelle P, et al. Management of Stable Ischemic Heart Disease: Summary of a Clinical Practice Guideline From the American College of Physicians/American College of Cardiology Foundation/American Heart Association/American Association for Thoracic Surgery/Preventive Cardiovascular Nurses Association/Society of Thoracic Surgeons. *Ann Intern Med*. 2012;157:735–743.
7. Department of Ayurveda, Siddha, Unani and Homeopathy (AYUSH). *Ayush in India*. Department of Ayurveda, Siddha, Unani and Homeopathy (AYUSH), Ministry of Health & Family Welfare, Govt of India; 2007.
8. Vinjamury SP, Vinjamury M, Sucharitul S, Ziegler I. Panchakarma: Ayurvedic detoxification and allied therapies—is there any evidence? *Evidence-based practice in complementary and alternative medicine*, Springer, Berlin, Heidelberg. 2012;113-137.
9. Annual Report. National Sample Survey Office. Available:<http://www.mospi.gov.in/national-sample-survey-office-nssso> (Last accessed 16 th August 2018)
10. Narasinga Rao BS: Nutrient requirement and safe dietary intake for Indians. *NFI Bull*. 2010;31:1–5.

11. Sinha K, Gaikwad S, Prabhakar M, Lohith BA. Critical review on role of panchakarma in sthaulya with special reference to obesity. *Int. J. Res. Ayurveda Pharm.* 2017;8(6):4-7.
12. Brehm BJ, Seeley RJ, Daniels SR, D'Alessio DA: A randomized trial comparing a very low carbohydrate diet and a calorie-restricted low fat diet on body weight and cardiovascular risk factors in healthy women. *J Clin Endocrinol Metab.* 2003;88(4):1617-1623. DOI: 10.1210/jc.2002-021480
13. Foster GD, Wyatt HR, Hill JO, McGuckin BG, Brill C, Mohammed BS, Szapary PO, Rader DJ, Edman JS, Klein S: A randomized trial of a low-carbohydrate diet for obesity. *N Engl J Med.* 2003;348(21):2082-2090.
14. Swati S. Deshpande et al. Panchakarma Approach to Sthoulya. *International Ayurvedic Medical Journal*; 2017. Available:http://www.iamj.in/posts/images/upload/3534_3539.pdf
15. 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 J.* 2017;69(3):299-304.
16. Liperoti R, Vetrano DL, Bernabei R, Onder G. Herbal medications in cardiovascular medicine. *J American Coll Cardiol.* 2017; 69(9):1188-99.
17. Choudhary K, Sharma P, Sharma V. Hypertension and its management through Panchakarma, *J of Ayurveda and Hol Med.* 2015;3(3):28-3.
18. Bhavamisra, Bhavaprakasa nighantu, Edited by Pandey GS; Chowkamba Bharathi Academy, Varanasi. 2013;292.
19. Lele SS, Macfarlane D, Morrison S, Thomson H, Khafagi F, Frenneaux M. Determinants of exercise capacity in patients with coronary artery disease and mild to moderate systolic dysfunction: Role of heart rate and diastolic filling abnormalities. *European heart J.* 1996; 17(2):204-12.
20. Lairikyengbam S, Davies A. Interpreting exercise treadmill tests needs scoring system. *BMJ.* 2002;325(7361):443.
21. César MD, Montesano FT, Diniz RV, Almeida DR, Tebexreni AS, Barros TL. Cardiopulmonary responses to exercise in patients of different age group with congestive heart failure. *Arquivos brasileiros de cardiologia.* 2006; 86(1):14-8

© 2019 Sane et al.; This is an Open Access article distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

Peer-review history:

The peer review history for this paper can be accessed here:
<http://www.sdiarticle3.com/review-history/46867>