

## Original Research Article

# Impact of Ayurveda-Based Panchkarma Therapy in Change of the VO<sub>2peak</sub> in Congestive Heart Failure Patients - An Observational Study

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### ABSTRACT

**Background and Aim:** Reduced peak oxygen uptake (VO<sub>2peak</sub>) is a primary predictor of mortality in congestive heart failure (CHF) patients, and it is also an indicator of an individual's exercise capacity. Traditionally, exercise training during cardiac rehabilitation has been used to improve the patient's VO<sub>2peak</sub>. However, this may not apply to patients of all ages due to exercise intolerance. Therefore, this study focused on using ayurveda-based panchakarma treatment to increase maximal oxygen consumption during regular physical activities.

**Methods:** An observational study was conducted on 589 CHF patients who had opted for panchakarma treatment at various branches of Madhavbaug clinics. The patient's weight, body mass index (BMI), and blood pressure (BP) were measured before the start of the treatment. A 6-minute walk test (6MWT) and cardiac stress test with modified Bruce protocol were used to measure the initial VO<sub>2peak</sub> value for each patient. Using this value, the initial metabolic equivalent was calculated. The study population underwent a minimum of 7 sittings (twice a day) of panchakarma therapy for seven days. They were asked to follow up after 90 days. During the follow up, their weight, BMI, BP, VO<sub>2peak</sub>, and metabolic equivalent (MET) were measured and compared with the results of day 1.

**Results:** The study consisted of 589 CHF patients aged 20 to 90 years, of which 53.24% were males and 46.76% were females. There was a weight reduction ( $3.28 \pm 1.24$ ,  $p=0.0001$ ), BMI ( $1.43 \pm 0.5$ ,  $p=0.0001$ ), and blood pressure, and an increase in the VO<sub>2peak</sub> ( $8.18 \pm 1.2$ ,  $p=0.0001$ ) and MET after the treatment. An age-wise comparison showed that the VO<sub>2 peak</sub> decreases with age and that the treatment's effect is seen more in younger patients. On the other hand, a similar improvement in oxygen consumption was seen in both genders. The treatment was also able to improve the VO<sub>2peak</sub> in patients with severe risk, i.e., those having an initial VO<sub>2peak</sub> value of <12mL/kg/min.

**Conclusion:** The ayurveda-based panchakarma treatment proved beneficial in improving the exercise capacity measured in VO<sub>2peak</sub> and MET, thus improving the exercise tolerance of the study population and reducing the risk of mortality.

*Keywords: Panchkarma, VO<sub>2peak</sub>, metabolic equivalent, exercise capacity, congestive heart failure, cardiac output.*

## 1. INTRODUCTION

**Congestive** heart failure (CHF) is considered to be a global pandemic with a prevalence of >37.7 million worldwide. [1] Congestive heart failure develops due to dysfunctions in either the left ventricular (LV) diastole or systole. This may develop due to various risk factors such as hypertension or metabolic syndromes, including diabetes mellitus, hyperlipidemia, and central obesity. [2]

These changes may be related to age. With increasing age, the changes in the heart's structure and function may affect the maximal stroke volume, thus decreasing the body's maximum oxygen consumption (VO<sub>2</sub>peak). VO<sub>2</sub>peak is the maximum oxygen uptake during physical activities like running and cycling. The oxygenated blood that is received by the heart needs to be pumped into the body. If the cardiac output is compromised due to dysfunctions of the left ventricle, there will be a load on the heart to compensate for the lower oxygen to the body, leading to CHF. [3] Patients with a low VO<sub>2</sub>peak show symptoms of dyspnea on exertion, and it is considered as the primary predictor of mortality in CHF patients. Thus, improving the VO<sub>2</sub>peak using certain interventions can reduce the mortality rate in heart patients. [4]

Another method of calculating the exercise intensity is the determination of metabolic equivalent (MET), which represents the baseline metabolic rate. It is the energy needed by an individual at rest. During an activity, the MET for an individual can be calculated by dividing the oxygen consumption (VO<sub>2</sub>) when performing the activity by the VO<sub>2</sub> at rest. [5]

Previous studies have shown an increase in the VO<sub>2</sub>peak during the 3-month intervention using cardiac care and exercise training. This increase in peak VO<sub>2</sub> led to the decrease in the all-cause mortality of the study population. However, it has been estimated that only 30% of patients reach the target number of training per week post 10-12 months. [6,7]

We have previously conducted studies on CHF patients who underwent panchakarma therapy to increase their maximal aerobic capacity (MAC). [8] Also, studies were carried out to evaluate the efficacy of the treatment on VO<sub>2</sub>peak. [9] This study, however, is a detailed analysis of the change in the VO<sub>2</sub>peak regarding three groups based on age, initial value of VO<sub>2</sub>peak, and gender.

## 2. MATERIAL AND METHODS

### 2.1 STUDY POPULATION

An observational study was carried out on a group of patients (aged 20-90 years, both genders included, N=589) suffering from CHF from 217 centers of Madhavbaug clinic all over India between **January 2019 and September 2019**.

Inclusion criteria: Known CHF patients who complied with the New York Heart Association (NYHA) class I to III were included in the study.

Exclusion criteria: CHF patients who belonged to NYHA class IV and those who were contraindicated for cardiac stress testing were excluded.

### 2.2 STUDY EVALUATION

At the start of the study, the known CHF patients were screened according to the New York Heart Association (NYHA) classification. Patients were included as per the study criteria mentioned above. Their weight, BMI, and blood pressure (BP) were noted. Using the 6-minute walk test (6MWT) method, the VO<sub>2</sub>peak and metabolic equivalents (MET) were calculated based on Cardiac Stress Testing with Modified Bruce Protocol. Then the average for the study population was calculated. After 90 days, the weight, BMI, BP, VO<sub>2</sub>peak, and MET were measured, and the average was compared to the average of day 1.

## 2.3 STUDY THERAPY

The study population was given a minimum of 7 sittings twice a day of ayurvedic-based herbal **therapies** for seven days to a maximum of 21 sittings for 90 days. The therapy consists of 4 steps- centripetal oleation, thermal **vasodilation**, thoracic drip and per rectal herb decoction administration [10].

- Centripetal oleation (Snehana): This step includes massaging the patient using sesame oil containing the essence of lavender oil. The patient is made to lie on his back, and the massage is carried in a circular manner from the wrist towards the heart, up to the abdomen in clockwise and anticlockwise directions. The same procedure is followed for the back. Also, the vertebral column is massaged from the lumbar region towards the cervical region in a zigzag manner. The duration of this step is 20 minutes
- Thermal **vasodilation**: The patient lies supine in a sudation box during this procedure. Steam (temperature maintained at 40°C) generated by the boiling of Dashmoola (**roots of ten specific herbs described as Dashmoola**) decoctions is allowed to flow uniformly in the closed box for 10-15 minutes. The patient is then made to relax in the box for 3-4 minutes. The entire procedure takes 20 minutes.
- Thoracic drip: A warm dashmoola decoction is allowed to drip over the patient's thoracic cavity (7-8 cm height) with constant speed. This procedure takes 15 minutes to complete.
- Per rectal herb decoction administration: A decoction (10 ml aqueous extract) is prepared with a mixture of T. arjuna (1880 mg) and B. diffusa (420 mg). This decoction is filled in an enema can, and the decoction is administered into the rectum of the patient. This procedure lasts 10 minutes, and the solution must be retained in the body for at least 15 minutes for maximum absorption.

The study was approved by the institutional review board and conducted in compliance with the ethical standards of the responsible institution on human subjects and with the Helsinki Declaration.

## 2.4 STATISTICAL ANALYSIS

**The data collected were analyzed using the one-way Analysis of variance (ANOVA) test in Microsoft Excel.** The mean  $\pm$  standard deviation (SD) data of the study population recorded for the various parameters on days one and 90 were compared. Comparison of the change in the VO<sub>2</sub>peak before and after the treatment were divided into three categories- Age group-wise VO<sub>2</sub>peak distribution, the value of initial VO<sub>2</sub>peak, and gender group-wise VO<sub>2</sub>peak. The mean  $\pm$  SD values were plotted on graphs to compare the effect of the treatment on the VO<sub>2</sub>peak.

### 3. RESULTS

#### 3.1 STUDY POPULATION

A total of 647 CHF patients were screened, of which 589 patients from 217 centers all over India (West zone: 357, South zone: 82, and North zone: 150) were selected based on the inclusion criteria. The population consisted of 269 (46.76%) females and 320 (53.24%) males belonging to the age group of 20 to 90 years. Along with CHF, some patients were suffering from diabetes mellitus (DM) (18%), Hypertension (HTN) (14.43%), and obesity (8.49%).

#### 3.2 STUDY EVALUATION

All investigations carried out before and after the treatment

The mean results of day one and day 90 were tabulated and compared. A decrease was observed in the study population's average weight, BMI, and BP. The oxygen consumption measured in VO<sub>2peak</sub> and MET increased post-treatment. (Table 1)

Table 1: Change in the investigations carried out before and after the treatment.

Test Performed	Day 1 (mean ± SD)	Day 90 (mean ± SD)	P-value
Weight (kg)	69.47 ± 13.80	66.19 ± 12.56	0.0001
BMI (kg/cm <sup>2</sup> )	27.50 ± 4.92	26.07 ± 4.42	0.0001
SBP(mm Hg)	128.68 ± 13.37	121.46 ± 14.60	0.0001
DBP (mm Hg)	79.75 ± 11.	76.07 ± 8.58	0.0001
VO <sub>2peak</sub> (mL/kg/min)	16.74 ± 7.47	24.65 ± 8.67	0.0001
MET	4.78 ± 2.13	7.07 ± 2.47	0.0001
Index: BMI- Body mass index, SBP- systolic blood pressure, DBP- diastolic blood pressure, MET- metabolic equivalent, SD- standard deviation			

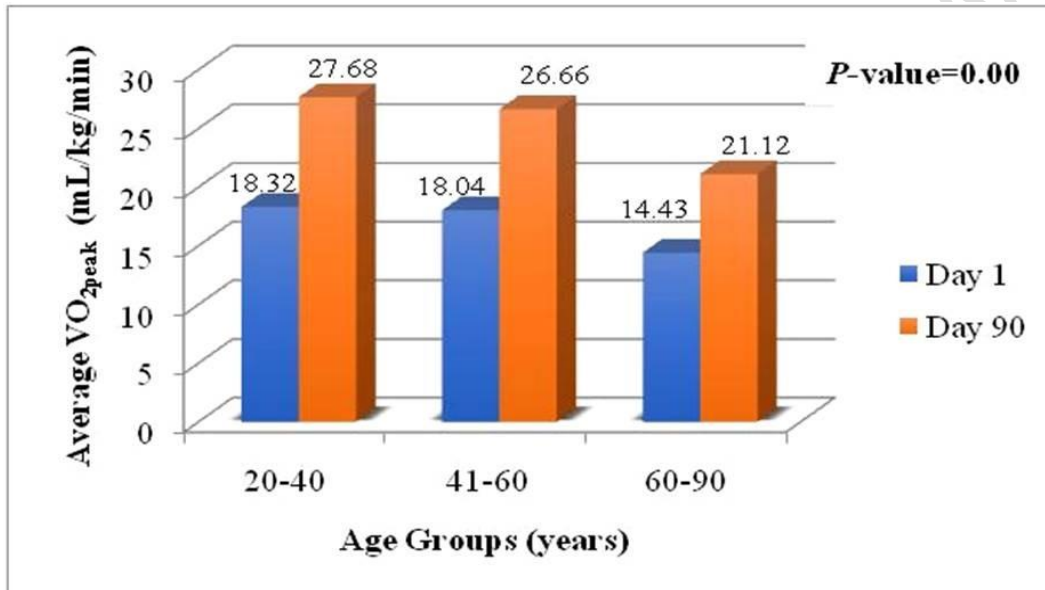
The treatment reduced medication for the study population, with the only exception being the antiplatelet medicine. The highest reduction is seen in proton pump inhibitors (PPI) and calcium channel blockers (CCB) allopathic medications.

Analysis of change in VO<sub>2peak</sub> within different study groups.

The study population was divided into 3 study groups based on age, initial VO<sub>2</sub>peak value, and gender.

- Age group wise VO<sub>2</sub>peak distribution:

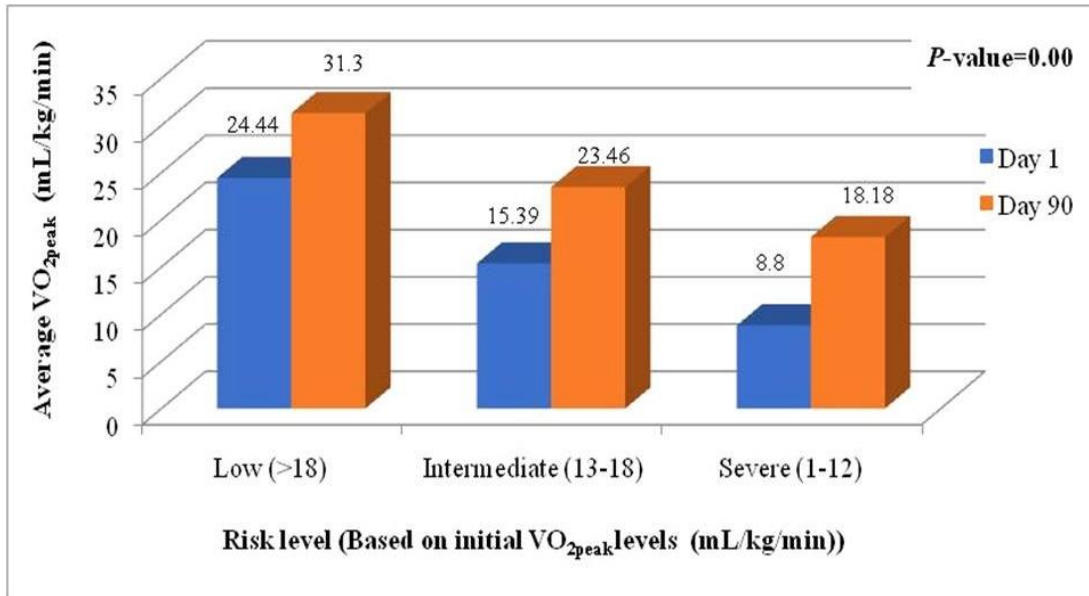
The study population was divided into three groups: age- 20-40 years, 41-60 years, and 61-90 years. It was observed that the initial value of the average VO<sub>2</sub>peak decreased with increasing age groups. Also, the increase in VO<sub>2</sub>peak post-treatment varied among the three groups, with 20-40 years showing the highest change (9.36 mL/kg/min) followed by 41-60 years (8.62 mL/kg/min) and the lowest change in 61-90 years (6.69 mL/kg/min). (Figure 1)



**Figure 1:** Change in the average VO<sub>2</sub> peak in the study population between different age groups post-treatment.

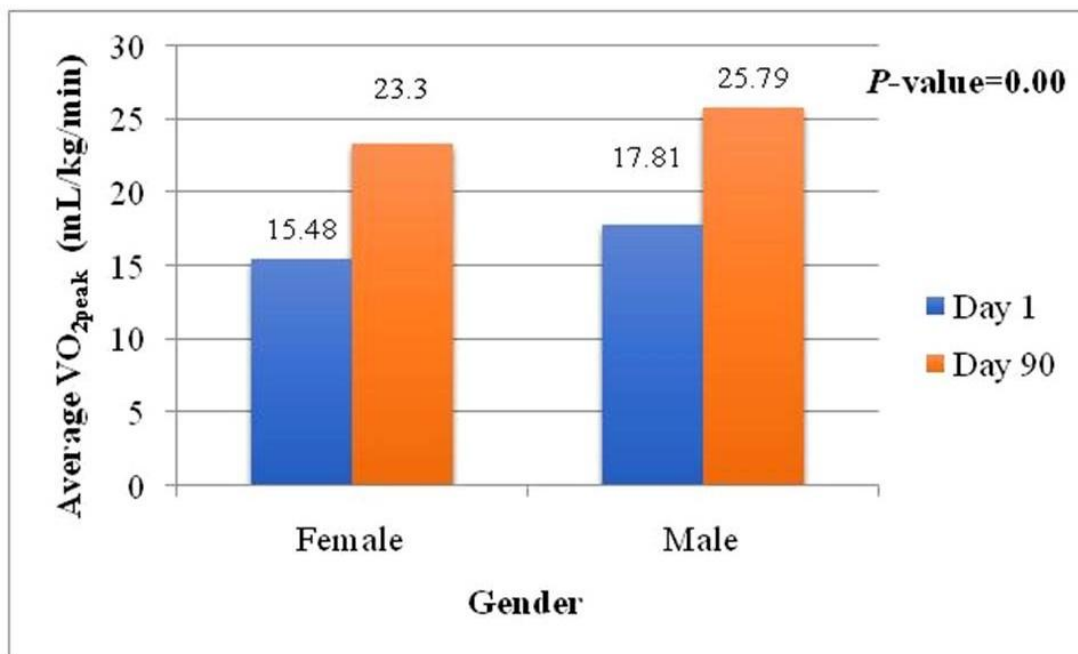
- Initial VO<sub>2</sub>peakGroup distribution:

Additionally, similar to the study conducted by Keteyian SJ et al. 2008 [10], we divided the study population according to the initial values of VO<sub>2</sub>peak of each patient into three groups- Severe (1-12 mL/kg/min), Intermediate (13-18 mL/kg/min) and low risk (>18 mL/kg/min). The change in oxygen consumption post-treatment within each group was studied. The increase in VO<sub>2</sub>peak value of patients under the severe group (9.38 mL/kg/min) was higher compared to intermediate (8.07 mL/kg/min) and low-risk (6.95 mL/kg/min) patients. (Figure 2) This helped us understand the study therapy's efficacy in patients with different severity.



**Figure 2:** Risk profile of study population based on initial VO<sub>2peak</sub> value at baseline (day 1) and Day 90.

Gender group-wise VO<sub>2peak</sub> distribution: A similar improvement in the VO<sub>2peak</sub> was observed in the female group (7.82 mL/kg/min) and male group (7.98 mL/kg/min). (Figure 3)



**Figure 3:** Change in the average VO<sub>2peak</sub> in the female and male study population post-treatment

Medicine reduction: The dependency of the study population on allopathic medicines for blood pressure, heart failure, and diabetes reduced considerably (Table 2).

**Table 2:** Change in the medication of the study population after the treatment.

Allopathic medicine	Day 1*	Day 90*	Medicine Reduction (%)
Beta Blocker	139	93	33.09
ARNI	16	8	50.00
ACE inhibitor	31	19	38.71
Sulfonylurea	81	51	37.04
Biguanide	118	78	33.90
Dpp 4 Inhibitor	21	13	38.10
CCB	56	25	55.36
PPI	42	15	64.29
Nitrate	62	30	51.61
Antiplatelet	224	147	77.00
Vasodilator	22	15	31.82
<p>*Values indicate the number of patients that were prescribed the medication.</p> <p>ARNI-Angiotensin receptor-neprilysin inhibitor, ACE- Angiotensin-converting enzyme, DPP- dipeptidyl peptidase, CCB- calcium channel blockers, PPI- proton pump inhibitors, NSAID- nonsteroidal anti-inflammatory drugs</p>			

#### 4. DISCUSSION

We conducted an observational study on 589 CHF patients who had approached the different branches of Madhavbaug clinics all over India. The patients were considered for the study based on their NYHA classification.

On Day 1, the weight, BMI, and BP were measured. 14.43% of patients were hypertensive, and it was needed to treat the high BP as well. On day 1, the patients underwent a 6 MWT, during which the VO<sub>2</sub>peak was measured. The MET values for each patient were calculated using the maximum oxygen consumption. The value of VO<sub>2</sub>peak was divided by 3.5 (resting VO<sub>2</sub>) to obtain the value of MET. [12] The therapy helped to reduce the weight and BMI. The centripetal massage improves blood circulation and helps remove toxins from the cells via the lymphatic system. The rise in body temperature caused by the steam leads to an increase in the rate of metabolism, thus leading to an increase in the generation of waste

products. The steam also causes the body vessels to expand, enabling improved circulation and transfer of the toxins to the gastrointestinal (GI) tract. [13]

During rectal herbal decoction administration, the herbal decoction may enter into systemic circulation that might have cardiac-specific activity, thereby imparting cardiogenic action on the myocardium. A double-blind crossover study reported potential cardiogenic properties of one or more constituents of the herb T. Arjuna (glycosides) that is also used in per rectal herbal decoction administration procedure included in the current study protocol [14,15]. The additional two herbs used in per rectal herbal decoction administration are B. Diffusa and A. Calamus. B. Diffusa is reported to have a cardioprotective effect owing to its protective effect against mitochondrial dysfunction, which plays a critical role in cardiac hypertrophy or heart failure. An animal study reported the cardioprotective effect of A. Calamus by increasing the antioxidant enzyme levels glutathione, catalase, and superoxide dismutase and decreasing malondialdehyde levels. Additionally, the herb A. Calamus has also been reported to have hypolipidemic activity.

CHF leads to patients having a limited exercise capacity, and this exercise intolerance is associated with a higher risk of mortality. [18] It is therefore important to increase the exercise capacity using different interventions. Traditionally, exercise training is used to help CHF patients increase their exercise tolerance.

Panchakarma therapy is known to improve the left ventricular systolic and diastolic dysfunction, which increases the cardiac output, thus improving the VO<sub>2</sub> peak.[10] In this study, we compared the increase in the VO<sub>2</sub> peak after treatment between 3 groups based on age, initial value of VO<sub>2</sub> peak and gender.

It was observed that with increasing age, the initial VO<sub>2</sub> peak values decrease. This corresponds to previous findings wherein a 10% per decade decrease was seen after the age of 25 years and a 15% reduction between the ages of 50 and 75 years.[19] Additionally, our therapy is also designed to activate the attenuated muscle tissues in the young population. However, the same in elderly patients is not possible due to quantitative muscle loss related to aging. Therefore, the results of the current study might seem more promising for young CHF patients as compared with the older ones.

Next, the study population was divided based on the initial value of VO<sub>2</sub> peak- Severe (1-12 ml/kg/min), Intermediate (13-18 ml/kg/min), and low risk (>18 ml/kg/min). The therapy helped to increase the VO<sub>2</sub> peak value of the severe and intermediate-risk groups to more than 18 ml/kg/min, thus lowering the risk of mortality.

The initial oxygen consumption in females was less than that of males. Women have more fat than muscle as compared to men, so this results in a lower VO<sub>2</sub> peak in females. Also, haemoglobin content in men is higher than that in women, leading to a higher oxygen-carrying capacity and, hence, higher oxygen consumption. [20] It was observed that the increase in oxygen consumption post-therapy was almost the same between men and women. Thus, the treatment showed similar effects in both men and women.

The study population who were prescribed different allopathic medicines at the beginning of the study reported to have reduced dependency on these medications post-therapy. The prescriptions of antihyperglycemic agents were found to have tapered based on continuous blood sugar level measurements and blood pressure. Post therapy, the prescribed dosage/strength of vasodilators was reduced as compared to before treatment based on the

reduction in angina pectoris. Additionally, the Angiotensin Receptor-Neprilysin Inhibitor (ARNI) was tapered to almost 50% based on the symptoms and follow-up NT-proBNP levels.

Limitations: Although the study sample size was appropriate to arrive at a plausible conclusion, the age and gender-matched control arm was not present to make a head-to-head comparison. Further, being an observational single-arm study, this study design had built limitations of not being a randomized and controlled study.

## **5. CONCLUSION**

The observational study was carried out on 589 CHF patients to assess the effect of the ayurveda-based panchakarma treatment on the increase in oxygen consumption. The treatment led to a reduction in BMI, thus reducing the burden on the heart to supply adequate oxygen during regular activities. Patients with CHF have reduced exercise tolerance, and our study also focused on using panchakarma to increase their exercise intensity measured in MET. We concluded that the increase in  $VO_{2peak}$  is dependent on age but independent of gender. Also, all the patients reached the low-risk category of more than 18 ml/kg/min of  $VO_{2peak}$  irrespective of their initial maximum  $VO_2$ . Also, the therapy reduced the dependency on allopathic medication. The patients were, therefore, less dependent on medicines to maintain their health and could carry out regular physical activities due to increased exercise capacity.

## 9. CONSENT (WHERE EVER APPLICABLE)

Consent to participate: Informed consent from each participant was registered

Consent for publication Non-disclosure of personal information was agreed, and consent for research publication was obtained.

## 10. ETHICAL APPROVAL (WHEREVER APPLICABLE)

Institutional review board approval and in compliance with the ethical standards of the responsible institution on human subjects as well as with the Helsinki Declaration

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