

Original Article

Effect of Heart Failure Reversal Therapy Program (HFRT) on Chronic Heart Failure Patients: A Retrospective Study

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Abstract

Background: Chronic heart failure (CHF) is a major health issue despite of the available medications. Heart failure reversal therapy (HFRT), a combination of herbal treatment and allied therapies, has been advocated by Ayurveda physicians as an add-on therapy for CHF.

Aim: The present study was conducted to evaluate the effect of HFRT on Maximum Aerobic Capacity (MAC), blood pressure (BP), body mass index (BMI) and dependency on conventional therapy in CHF Patients.

Materials & Methods: The present retrospective study was conducted in July 2017, wherein the data of CHF patients (New York Heart Association, NYHA Class I-IV) who attended out-patient departments (OPDs) at Madhavbaug clinics in Maharashtra, India were identified. Data of patients who were administered HFRT (60-75 minutes) with minimum 7 sittings over 90 days (± 15 days) were considered. Variables were compared between day 1 and day 90 of HFRT.

Observations and Results: Out of 79 patients included, 39 were males while 40 females. HFRT showed significant improvement in MAC by 50.35% (from 18.60(± 7.01) to 27.97(± 7.98), $p < 0.01$) with maximum improvement in NYHA Grade IV patients ($n=14$) [change by 145.90% (from 7.46 to 18.36, $p < 0.01$)]. BMI [27.78(± 5.50) kg/m² to 26.61(± 4.84) kg/m²], systolic and diastolic blood pressure [134.4(± 17.2) mm Hg to 122.5(± 9.74) mm Hg and 82.75 (± 7.13) mm Hg to 77.97(± 10.73) mm Hg, ($p < 0.01$) respectively] showed significant reductions. Dependency on concomitant medicines was reduced, with number of patients on no concomitant medicines increasing from 19% to 42%.

Conclusion: HFRT can be an effective option for management of CHF patients, along with conventional allopathic medications.

Keywords: *Alternative medicine, Chronic heart failure, Heart failure reversal therapy, Maximum aerobic capacity, Panchakarma*

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Citation

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Introduction

Cardiovascular diseases (CVDs) have become an important cause of mortality and morbidity worldwide and their epidemiological transition in India in the last two decades has been shocking. In fact, CVD has become the leading cause of death in India. [1] Among the many CVDs affecting the population, chronic heart failure (CHF) is a health issue of serious concern due to the growing number of people being plagued by it. As per estimates, a whopping 8-10 million people in India are suffering from CHF, with an approximate prevalence of 1% population. [2] There are established guidelines in place with multiple classes of pharmacological agents like angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), beta blockers and vasodilators being recommended for the treatment of CHF. [3] However, despite of these multiple choices of drugs, the post-admission mortality in India for patients of CHF is 20% to 30%. [3] The medication adherence has also been found to be only between 25% to 50%, with Indian patients specifically having low tolerance to these drugs used for CHF management. [3] Hence, there is a clear need of new treatment modalities which will not only alleviate the poor prognosis of CHF, but will also decrease the anxiety and the fear associated with the disease and boost the quality of life of the patient.

The treatment of CHF is complex due to multiple factors like old age, multiple medicines, comorbidities as well as the mental depression associated with the disease. [4] The benefit of drug classes like beta blockers and ARBs in treatment of CHF has been attributed to their anti-inflammatory as well as anti-oxidant property. [5-6] Multiple herbal drugs have been found to have anti-oxidant and anti-inflammatory properties as well, which make them interesting research contenders for assessment in CHF. [7-11]

Ayurveda physicians believe in prescribing conventional drugs in the acute disease phase while in the chronic stage of heart failure, use of *Panchakarma* therapy (a 5-step process for providing internal body purification) has been advocated as an add-on therapy. [12] Heart failure reversal therapy (HFRT) which can also be known as *Sampurna Hruday Shudhikaran* (SHS) therapy, is a combination of herbal treatment with *Panchakarma* and allied therapies. [13-15] The techniques used are *Snehana* (Oleation), *Swedana* (passive heat therapy), *Hrudaydhara* (Concoction dripping treatment) and *Basti* (Per rectal drug administration) among the *Panchakarma*, which are known to remove toxins from the body. [12], [16]

Functional capacity of a person describes his ability to perform exertional activities. CHF is associated with impaired functional capacity, indicated by the decrease in the maximal aerobic capacity (MAC). [17] The reduced MAC will also diminish the ability to perform daily living activities and hence, the quality of life (QoL) will be compromised. [18] Hence, a retrospective study was planned to evaluate the effect of HFRT as an add-on therapy to the standard treatment on the MAC in patients with CHF. This study also assessed the effect of HFRT on the body mass index (BMI), systolic blood pressure (SBP), the diastolic blood pressure (DBP) and the dependency of these CHF patients on the conventional therapy.

Material and Methods

This was a retrospective study conducted between July 2017, data of patients suffering from CHF (New York Heart Association, NYHA Class I-IV) of either gender of any age, and who had attended the out-patient departments (OPDs) at multiple Madhavbaug clinics located in various cities of Maharashtra, India were considered for study. The data of patients who had been administered HFRT with minimum 7 sittings over a span of 90 days (± 15 days) with each sitting lasting up to 65-70 mins were considered for the study. Cases were identified, and data was assessed from the records of Madhavbaug clinics in Maharashtra. The selection was based upon the availability of complete relevant baseline data (day 1 of HFRT) and final day data (day 90 of HFRT) of the patients. The information about prescribed concomitant medicines or comorbidities, if any, was also noted down. The HFRT is a 4-step procedure which was performed on the patients of CHF after a light breakfast. One sitting of the procedure took 65-75 minutes, as described in table no.1. [12], [16]

On day 1 of HFRT, the patients had undergone Cardiac Stress Testing by Modified Bruce Protocol. [19] 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, which is nothing but MAC. This process was repeated on day 90 of HFRT to calculate MAC. The other baseline and day-90 data which were considered retrospectively by investigators for the inclusion of the patients included BMI, SBP, DBP and the conventional treatment information. The BMI for day 1 and day 90 of the patients was calculated by checking the weight and the height from the medical data sheets of patients and using the formula: $\text{weight in kilograms}/(\text{height in meters})^2$. Similarly, the baseline and the day-90 readings of SBP and DBP were noted down from the medical records of the enrolled patients.

Table no.1: Study Treatment: Heart Failure Reversal Therapy (HFRT)

Step of HFRT	Type of Therapy	Herbs used for therapy	Time Duration
<i>Snehana</i>	Massage or external oleation of whole body (centripetal upper strokes directed towards heart)	10 grams <i>T. arjuna</i> , 10 grams <i>Dashmoola</i> and 5 grams <i>Vnegundo</i> [100 ml extract processed in sesame oil]	30-35 minutes
<i>Swedana</i>	Passive heat therapy Hrudya (heart) was protected from direct exposure of steam flow.	<i>Dashmoola</i> (group of ten herbal roots) with steam at ≤ 40 degrees Celsius)	10-15 minutes + 3-4 minutes of relaxation after procedure (patients were advised to sit without performing any activity after <i>Swedana</i>). ECG and BP measured before and after therapies to note for any adverse changes.
<i>Hrudaydhara</i>	Decoction dripping therapy from a height of 7-8 cm	Luke-warm <i>Dashmoola</i> decoction	15 minutes
<i>Basti</i>	Medicated enema administered perrectal, should be in body for ≥ 15 minutes for maximum absorption	1.88 grams <i>T. arjuna</i> , 0.42 grams <i>B. diffusa</i> and 0.18 grams <i>A. calamus</i> [10 ml aqueous extract]	10 minutes

The dependency on standard medication was calculated both on day 1 and day 90 of HFRT 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.

In this study, data were collected and entered using Microsoft excel. Categorical data were expressed in terms of percentage and continuous data were expressed as Mean \pm SD. R Version 3.4.1 software was used to analyses the data. Paired t test was used to check before and after 90 days effect of HFRT treatment. The improvement in MAC, BMI and BP as well as the reduction in dependency on concomitant standard medications were expressed as percentages.

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The BMI for day 1 and day 90 of the patients was calculated by checking the weight and the height from the medical data sheets of patients and using the formula: $weight \text{ in kilograms} / (height \text{ in meters})^2$.^[2] Similarly, the baseline and the day-90 readings of SBP and DBP were noted down from the medical records of the enrolled patients. The dependency on standard medication was calculated both on day 1 and day 90 of HFRT 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.

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Observations

Study population:

A total of 232 patients' data was screened for inclusion in the study. However, based on the availability of data (Day 1 and Day 90) and the inclusion criteria, data of

79 patients were selected, and was considered for analysis. The baseline characteristics of these patients are shown in table no. 2. Baseline data included gender, age, height of the patients and New York Heart Association (NYHA) functional class.

Table no.2: Baseline characteristics of the study subjects (n= 79)

Variable	Mean ± SD
Gender (M/F)	39/40
Age (Years)	54.88±11.75
Height (cm)	158.77± 9.21
Past medical history Frequency (%)	
Hypertension	30 (37.97)
DM	19 (24.05)
Percutaneous transluminal coronary angioplasty-	4 (5.06)
MI	2 (2.53)
Hypothyroidism	4 (5.06)
NYHA functional class Frequency (%)	
Class I	19 (24.05)
Class II	28 (35.44)
Class III	18 (22.78)
Class IV	14 (17.72)

Results

Effect of HFRT treatment on improvement of body parameter is summarized in Table no.3. In all 79 cases, HFRT treatment showed significant improvement in all body parameters. There was highly increment in MAC, MET ($p<0.001$) and reduction in weight, BMI, SBP and DBP ($p<0.001$).

In NYHA Grade I, Weight was significantly reduced in 90 days of post treatment ($p=0.001$). Treatment shows a significant improvement on Maximum Aerobic Capacity (MAC) and MET ($p <0.001$) whereas, it showed significant reduction in BMI ($p=0.002$), SBP ($p=0.031$) after treatment. There was no statistical significant difference in DBP after treatment ($p=0.162$).

In NYHA Grade II; MAC, MET was significantly improved ($p <0.01$) and reduction in weight, BMI,

NYHA Grade III; MAC, MET was significantly improved ($p<0.001$), whereas significant reduction in weight ($P=0.032$), BMI ($p=0.047$) and SBP ($p= 0.005$) was noted, there was no difference in DBP before and after treatment ($p=0.082$).

Similarly, NYHA Grade IV; MAC and MET were highly increased ($p<0.001$), this study shows significant reduction in weight ($p=0.031$), BMI ($p=0.009$), SBP ($p=0.001$).

Dependency of medicines was reduced post treatment of 90 days for all medicines and highly reduced in ARA+ ARB, Beta Blocker, CCB, Statins, Nitrate (Table no. 4).

Discussion

CHF is a major cause of mortality all over the world despite the presence of multiple treatment options for the same. There is surely a need for new management options for CHF which turns the attention towards alternative medicine. The conventional drugs like beta blockers have been found to have anti-oxidant and anti-inflammatory properties which are responsible for the benefit in CHF. Multiple herbal drugs have been found to have these properties and thus, Ayurveda seems a viable alternative option for research in patients of CHF. Ayurveda physicians use *Panchakarma* as an add-on therapy for treatment of CHF and HFRT is a combination of *Panchakarma* with allied therapies.^{[15]-[18]} Therefore, we assessed the effect of HFRT in patients of CHF and found that the functional capacity (MAC) had significantly improved at the end of 90 days of the procedure. HFRT also showed a significant decrease in the BMI, SBP and DBP at the end of 90 days when compared to the baseline mean values. The dependency on standard allopathic medications at the end of 90 days was also decreased in these patients who had received HFRT.

Functional capacity, measured by assessing the MAC, is an indicator of the cardiorespiratory function of an individual. A compromised MAC is noted in patients of CHF and the extent of decrease indicates the severity of the disease.^[20-22] In our study, the MAC was found to be significantly improved at the end of 90 days, thereby indicating a betterment in the exercise capacity of the patient. MAC is an independent predictor of mortality in chronic heart disease.

A retrospective study in patients suffering from coronary heart disease reported that 1-unit (mL/kg/min) increase in VO_2 peak is associated with 15% reduction in mortality. Hence, the significant MAC improvement in our study by HFRT indicates a better prognosis in patients with cardiac morbidity.

Table no.3: Effect of HFRT treatment on improvement of various body parameters according to overall and NYHA subjects

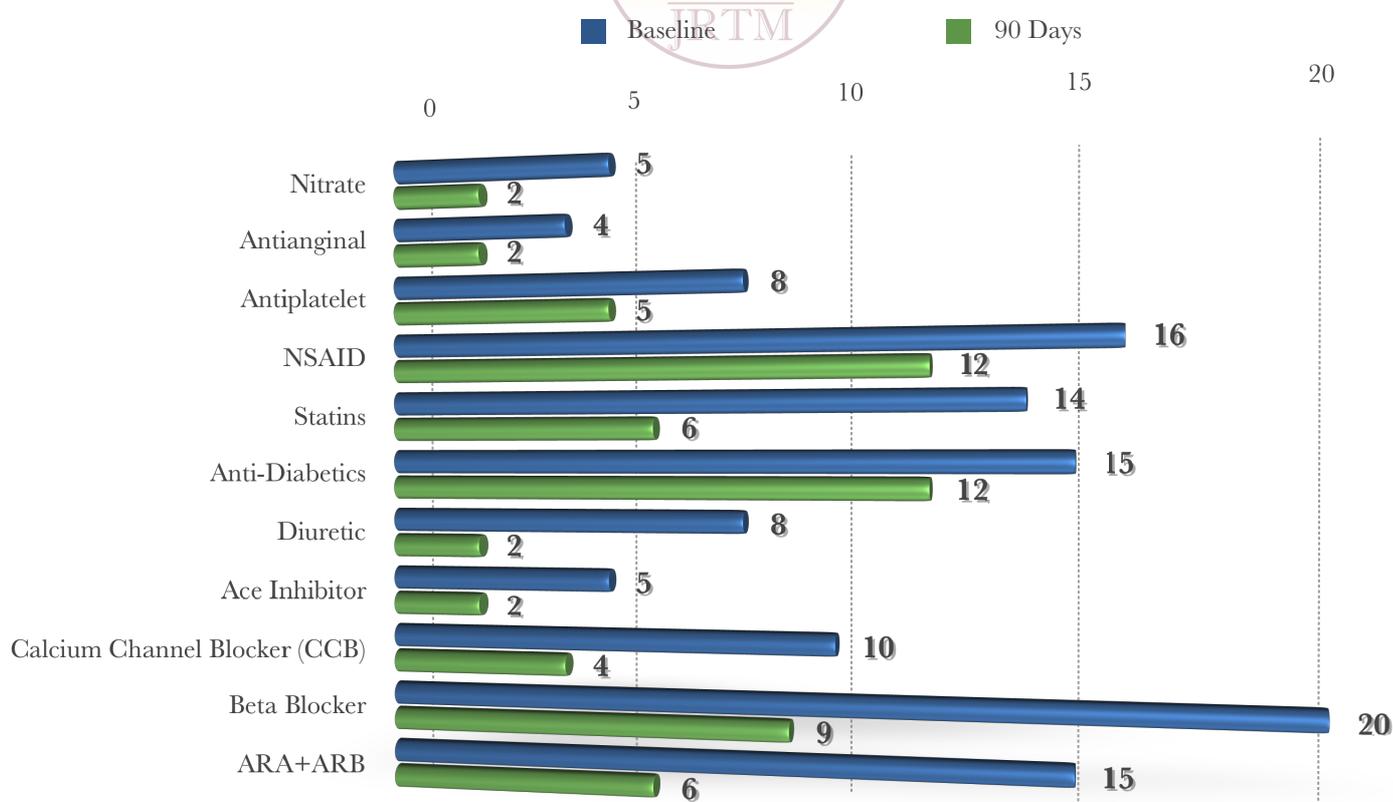
Classification	Variable	Baseline value (Mean \pm SD)	After 90 days (Mean \pm SD)	P- value
All (n=79)	Weight (kg)	70.49 \pm 16.13	67.93 \pm 14.53	<0.001
	MAC	18.6 \pm 7.01	27.97 \pm 7.98	<0.001
	MET	5.32 \pm 2.00	7.99 \pm 2.28	<0.001
	BMI	27.78 \pm 5.50	26.61 \pm 4.84	<0.001
	SBP	134.4 \pm 17.2	122.5 \pm 9.74	<0.001
	DBP	82.75 \pm 7.13	77.97 \pm 10.73	<0.001
NYHA I (n=19)	Weight (kg)	69.26 \pm 14.44	65.96 \pm 12.69	0.001
	MAC	26.88 \pm 2.47	33.38 \pm 3.21	<0.001
	MET	7.68 \pm 0.72	9.54 \pm 0.92	<0.001
	BMI	26.51 \pm 4.21	25.51 \pm 3.97	0.002
	SBP	130 \pm 13.74	121.5 \pm 7.65	0.031
	DBP	81.37 \pm 4.72	78.6 \pm 6.15	0.162
NYHA II (n=28)	Weight (kg)	73.35 \pm 14.7	69.97 \pm 14.11	<0.001
	MAC	21.32 \pm 1.37	29.80 \pm 5.48	<0.001
	MET	6.09 \pm 6.40	8.51 \pm 1.56	<0.001
	BMI	28.66 \pm 4.62	27.26 \pm 4.71	<0.001
	SBP	136.93 \pm 19.67	122.22 \pm 11.55	<0.001
	DBP	84 \pm 6.88	78.3 \pm 5.67	0.001
NYHA III (n=18)	Weight (kg)	69.18 \pm 19.76	67.88 \pm 15.95	0.032
	MAC	14.29 \pm 1.72	26.88 \pm 7.33	<0.001
	MET	4.08 \pm 0.49	7.68 \pm 2.09	<0.001
	BMI	27.24 \pm 7.01	26.36 \pm 5.70	0.047
	SBP	136.11 \pm 15.39	123.88 \pm 8.49	0.005
	DBP	82.78 \pm 7.52	79.44 \pm 4.16	0.082
NYHA IV (n= 14)	Weight (kg)	68.35 \pm 16.46	66.37 \pm 16.89	0.031
	MAC	7.46 \pm 1.88	18.36 \pm 9.16	<0.001
	MET	2.14 \pm 0.53	5.25 \pm 2.62	<0.001
	BMI	28.45 \pm 6.57	27.18 \pm 5.22	0.009
	SBP	133.14 \pm 18.97	122.72 \pm 11.04	0.001
	DBP	82.14 \pm 9.75	81 \pm 7.38	0.095

NYHA = New York Heart Association, MAC = Maximum Aerobic Capacity, MET = Metabolic Equivalents, SBP = Systolic Blood Pressure, DBP = Diastolic Blood Pressure

Table no. 4: Dependency on concomitant standard medications

Medicine	Baseline Frequency (%)	After 90 days Frequency (%)
Aldosterone Receptor Antagonists + Angiotensin Receptor Blockers	15 (26.79)	6 (10.71)
Beta Blocker	20 (35.71)	9 (16.07)
Calcium Channel Blocker (CCB)	10 (17.86)	4 (7.14)
ACE inhibitor	5 (8.93)	2 (3.57)
Diuretic	8 (14.29)	2 (3.57)
Anti-diabetics	15 (26.79)	12 (21.43)
Statins	14 (25)	6 (10.71)
NSAID	16 (28.57)	12 (21.43)
Antiplatelet	8 (14.29)	5 (8.93)
Antianginal	4 (7.14)	2 (3.57)
Nitrate	5 (8.93)	2 (3.57)
No Allopathy medicines	11 (19.64)	24 (42.86)

Figure no.1: 56 Subjects using Allopathy medicines



BMI is considered as an indicator of sedentary lifestyle and obesity, and CHF patients having high BMI are at greater risk of mortality.^{[24],[25]} Hypertension is a known risk factor for development of CHF and hence, strategies have been developed to provide sustained blood pressure control in hypertensive patients, to prevent CHF.^[26] In addition, various researchers have found out that elevated blood pressure in patients of CHF can lead to increased mortality.^[27] In this study, 60 of the 79 enrolled patients were suffering from hypertension, and hence it was important to assess the effect of HFRT on SBP and DBP. We found that HFRT causes significant decrease in the BMI, SBP and DBP of CHF patients. This also indicates that HFRT may cause a reduction in mortality of the CHF patients.

HFRT involves utilization of *Snehana* (External oleation or massage), *Swedana* (Passive heat therapy), *Hridaydhara* (Decoction dripping therapy) and *Basti* (Per rectal drug administration) that perhaps act in harmony to recover the parameters in patients of CHF. In chronic heart failure, there is a reduction in the cardiac output and an elevation in the work load which correspondingly elevates the oxygen usage by the left ventricle. The heart is unable to manage the upsurge in the demand and doesn't increase harmoniously. This leads to an upsurge in aerobic energy uptake and thus, a reduction in left ventricular efficiency.^[28] It is essential to preserve the oxygen demand of the body and the deteriorating heart, especially in cases of systolic dysfunction. It has been assumed that *Snehana* may reduce the sympathetic activity, leading to a reduction in the tone of the vasculature. *Swedana* leads to sweating which can be causing peripheral vasodilation and eventually a decrease in the systemic vascular resistance. The afterload eventually declines along with the decrease in the cardiac work load. An elevation in the body temperature because of passive heating also increases the cutaneous vascular conductance causing an elevated systemic conductance.^[29] *Hridaydhara* leads to mental and physical relaxation, thus having the positive effects on the cardio-respiratory parameters. According to a study including obese patients, *Basti* lessened the immune responses by modifying the pro-inflammatory cytokines, immunoglobulins and functional properties of T-cells. These alterations are related with a decrease in the body weight which is continued for a long period of time.^[30] This discovery may clarify the useful effect of *Basti* in patients with CHF.

The dependency of CHF patients on conventional allopathic medication shoots up the cost of treatment, which is a crucial issue in a developing country like India. Nevertheless, the exposure of patients to adverse effects of these drugs cannot be ignored. A study conducted in Canada revealed that elderly patients receiving CHF therapy suffer from adverse events at a greater frequency.^[28] Hence, it was thought of assessing the effect of HFRT on the dependency of these patients on conventional medications. It was found that a significant decrease in dependency, with an increase in the number of CHF patients who were not on any conventional allopathic medications at the end of 90 days.

The present study was a retrospective study and hence, prospective studies evaluating HFRT in CHF patients will help in producing a stronger evidence. The sample size was small and the period of follow-up was short. Studies with a larger sample size and long-term follow-up in patients with various levels of CHF severity can throw more light on the long-term implications of this promising treatment modality.

Conclusion

Treatment with HFRT showed a significant improvement in the functional capacity of CHF patients. HFRT also showed a substantially reduced dependency on conventional allopathic medications in these patients. A significant reduction in the BMI and the blood pressure by HFRT indicates a good prognosis in patients suffering from CHF. Hence, HFRT can be an effective option for the management of CHF patients, along with the conventional allopathic medications.

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