Case study

Evaluation of the efficacy of the Heart Failure Reversal Therapy (HFRT) in heart failure patients with reduced ejection fraction.

ABSTRACT

Background: Heart failure is a condition where the heart's ability to pump enough blood to support normal metabolic functions is impaired. This causes the heart's resting pressure to rise. Since it has afflicted about 26 million people globally, some authors believe that HF is currently pandemic. Heart Failure Reversal Therapy (HFRT) involves dietary control and herbal panchakarma therapy.

Aim: To study the effect of HFRT on ejection fraction in chronic heart failure patients with reduced ejection fraction.

Results: A total of 27 patients with HF and EF < 40% were enrolled in the study for analysis. There was a significant improvement in VO2peak, from 19.68ml/kg/min at baseline to 32.51ml/kg/min on day 90. The Mean ± SD on day 1 was19.68±8.84 which improved to 32.51±5.52. The VO2peak was statistically significant(p=0.00). Even more significant improvement was seen in ejection fraction which increased from 35% on Day 1(Mean ± SD = 35.54±12.32) to 53.4% on Day 90(Mean ± SD= 53.46±7.90) and it also showed statistical significance(p=0.00). Also, HR, BMI, abdominal girth, and weight showed similar statistically significant improvements. Improvements in SBP and DBP were not statistically significant.

Conclusion: Along with a reduction in body weight, BMI, and ABG, a significant rise in EF, VO2peak, and 6MWT was seen. For the treatment of HF with low EF, HFRT makes a strong case for consideration as an efficient therapeutic alternative.

Keywords: Heart failure, Ejection fraction, Heart Failure Reversal Therapy

INTRODUCTION

Heart failure is a condition where the heart's ability to pump enough blood to support normal metabolic functions is reduced, causing an increase in the heart's resting pressure.1The World Health Organization states that cardiovascular diseases (CVDs) are now the main cause of death and morbidity globally, and among all ethnic groups, Indians are thought to be the most severely impacted.2Compared to those of European heritage, CVD strikes the Indian population during their most productive midlife years and at least ten years earlier.3 Due to the vast number of people who are impacted by it, chronic heart failure (CHF), one of the many CVDs impacting the population, is a serious health concern. Chronic heart failure (CHF) care is a subject that has been extensively discussed for centuries, and there are well-established treatment plans that place a strong emphasis on the objectives of symptom reduction and prognosis improvement. The annual incidence of CHF in India ranges from 0.5 to 1.8 million, according to the rising global prevalence.4Increased sedentary lifestyle and other HF risk factors are directly related to India's rapid urbanization and industrialization over the past few decades. Due to population aging and patients with acute cardiovascular events having better prognoses, the burden of heart failure (HF) is gradually rising.5When the overall cardiac function is affected, HF can develop with reduced ejection fraction (HFrEF), and frequently the left ventricular ejection fraction is lower than 40%.The ejection fraction is retained in some HF patients (HF with preserved ejection fraction, HFpEF).

Several medications, including beta blockers, diuretics, angiotensin 2 receptor blockers, angiotensin-converting enzyme inhibitors, and anti-platelet medications, are available to treat HF.6HF has a poor prognosis despite the availability of a long list of conventional therapy alternatives. Patients who have HF experience the disease's symptoms directly as well as the fear and dread that goes along with them. The patient's quality of life is negatively impacted by these impacts. Given these circumstances, there is a need for innovative, more affordable therapy modalities that would lessen the patient's fear and anxiety and enhance their quality of life.

Ayurveda is regarded as a traditional medical method in India. The usefulness of panchakarma therapy in treating a variety of ailments has also been demonstrated by numerous research. Heart failure Reversal Therapy (HFRT) is a novel therapy created to improve patients with CHF's cardiorespiratory fitness. HFRT is a four-step procedure that includes Snehana (External Oleation Therapy), Swedana (Passive Heat Treatment), Hrudaydhara (Decoction Drip Therapy), and Basti (Per Rectal Administration).

In the present study, we have evaluated the efficacy of HFRT in patients with a reduced ejection fraction. The effect of HFRT along with a 1200Kcal diet programwas analyzed on ejection fraction(EF), VO2peak, systolic blood pressure (SBP),diastolic blood pressure(DBP), heart rate(HR), weight, body mass index (BMI), and abdominal girth(ABG) in patients withEF<40% to improve the quality of life of heart patients.

MATERIALS AND METHODS

a. Sample Size: 27

b. Study design: Observational.

c. Duration of study: November 2018 to October 2021

d. Study Site: Madhavbaug Cardiac Clinic, Dhantoli, Nagpur, India.

e. Inclusion Criteria: We have observed the efficacy ofthe HFRT program in:

- Elderly male and female patients = age group of 50 -75 years.
- Ejection fraction = ≤ 40%.
- NHYA Grade – II, III, and IV.

f. ExclusionCriteria: The following patients were excluded from the study:

- Patients having HF with a normal ejection fraction.
- Patients with acute illness.

g. Methodology:

A total of 32 patients were screened for the study out of which 3 patients discontinued the treatment and 2 patients expired due to COVID 19.We identified the data of 27 patients suffering fromHF (New York Heart Association, NYHA Class II, III, and IV)of age between 50-75 years, and who had attended the out-patientdepartments (OPDs) at Madhavbaug hospital locatedin Nagpur, Maharashtra, India. The data of patients who had been administered HFRT with a minimum of 7 sittings and a maximum of 21 settings over 90 days were considered for the study.The selection has been based on the patients' availability of complete relevant baseline data (day 1 of HFRT) to final day data (day 90 of HFRT). The information about comorbidities, if any, was also noted.

h. Primary endpoint –Left ventricular Ejection fraction(LVEF)

i. Secondary endpoints - VO2peak,weight,BMI,Abdominal girth,Heart rate,SBP, and DBP.

HFRT: The Panchakarma-based HFRT procedure (time required 65-75 minutes) was performed after a light breakfast on the patients in 7 sittingsover 90 days as described below:[7]

Snehana(Oleation)- A 30-35 minute massage therapy employing the sesame-oil-processed herbs Terminalia arjuna, Dashamoola, and Vitex negundo.

Swedana(Perspire) -The herb Dashmoola is used for a 10- to 15-minute passive heat therapy with steam at 40 degrees Celsius.

Hrudaydhara(Concoction dripping treatment)-A 15-minute decoction therapy that involves drips of Luke-warm Dashmoola.

Basti (Enema) - Employing the aqueous extracts of the plants Boerhavia diffusa, Acorus calamus, and Terminalia arjuna, a 10-minute medicated enema therapy.

Diet plan: Prameha diet box was provided to all the patients which included an 800kcal diet with high fibers, high proteins, and low carbohydrates and fats. It contained premixed medicines with food. Fluid restrictions to 1-1.5lit water/day were advised.

This study was conducted in accordance with the ethical principles of the Declaration of Helsinki, and all patients provided written informed consent.

Statistical analysis: A T-test was used to test statistically significant for primary endpoint improvement in EF, VO2peak, and secondary reduction in weight, BMI,ABG, heart rate SBD,DBP as well as a reduction in dependency on conventional medicine.

Table 1: Hypothesis for ANOVA test

Null hypothesis	Means are equal among all different time periods i.e. first visit and f/u 1st,f/u 2nd
Alternative hypothesis	means of at least2 groups are significantly different
Level of significance	0.00

RESULTS

A total of 32 patients' data was screened for inclusion in the study. However, based on the availability of data and the inclusion criteria, 27 patients were selected, and their data were considered for analysis. Out of which 65.38% were male patients. The mean age of the enrolled patients was57.69±8.69 years. Table 2 shows the data on past medical history and NYHA functional class.

Table 2: Frequency(%) of past medical history and NYHA functional class.

Past medical history Frequency (%)	
Coronary artery disease	6
Hypertension	20
Diabetic Mellitus	17
Ischemic heart disease	17
Myocardial infarction	9
NYHA functional class Frequency (%)	
Class I	0
Class II	17
Class III	9
Class IV	1

HFRT treatment and 1200kcal diet plan showed significant improvement in EF, weight, BMI, Abdominal girth, 6MWT (meters), and VO2peak in all 27 patients. For heart rate, SBP, and DBP, HFRT therapy was not statistically significant.Table 3 summarizes the impact of HFRT treatment on the improvement of body parameters.

Table 3: Effect of HFRT treatment on the improvement of various body parameters.

Variable	Sample size	Mean ± SD		P-value	Conclusions from ANOVA
		Day 1	Day 90		
ABG(cm)	26	89.97±14.89	83.41±13.94	0.00	Statistically significant

Weight(Kg)	26	67.16±11.82	61.42±9.37	0.00	Statistically significant
BMI(kg/m2)	26	25.22±3.52	23.12±2.94	0.00	Statistically significant
EF(%)	26	35.54±12.32	53.46±7.90	0.00	Statistically significant
6MWT (meters)	24	543.42±197.89	831.33±113.91	0.00	Statistically significant
Before HR (beats per minute)	24	82.46±15.26	74.71±10.89	0.02	Statistically insignificant
Before SBP (mmHg)	24	122.92±15.78	117.21±9.99	0.04	Statistically insignificant
Before DBP (mmHg)	24	73.63±7.99	71.63±7.44	0.14	Statistically insignificant
After HR (beats per minute)	24	111.67±22.42	126.13±18.13	0.02	Statistically insignificant
After SBP (mmHg)	24	146.08±24.76	146.08±20.52	0.99	Statistically insignificant
After DBP (mmHg)	24	80.96±10.36	84.25±9.06	0.18	Statistically insignificant
VO2peak (mL/kg/min)	25	19.68±8.84	32.51±5.52	0.00	Statistically significant

ABG – Abdominal girth, BMI – Body mass index, DBP - Diastolic blood pressure, EF – Ejection fraction, HR – Heart rate, SBP - Systolic blood pressure

The HFRT treatment showed statistically significant results for the primary endpoint (EF and VO2peak) and also for secondary endpoints (weight, BMI, ABG, and HR).SBP and DBP were statistically insignificant amongst secondary endpoints.

The HFRT and 1200Kcal diet plan was also found to be effective in the reduction of dependency on allopathic medicines. Table 4 shows data on the reduction of conventional medicines.

Table 4: Effect of HFRT treatment in the reduction of dependency on allopathic medicines.

Medicines	Day 1	Day 90	Medicines Tapering %
Calcium channel blockers	5	2	-60
Beta-blockers	20	7	-65
Vasodilators	5	3	-40
Diuretics	10	3	-70
Nitrate	7	2	-71.43
Angiotensin Receptor Neprilysin Inhibitor	1	1	0

DISCUSSION

The current observational study examined the impact of HFRT in elderly male and female patients with HF and discovered that from day 1 to day 7 of HFRT, EF and VO2peak significantly improved. Interestingly, these improvements persisted even on day 90 of follow-up. Secondary endpoints like weight, BMI, ABG, and HR also showed considerable improvement after HFRT. Due to a weak heart, oxygen intake in HF patients is significantly reduced. This is demonstrated by a decline in VO2peak.8Therefore, the present study's considerable improvement in VO2peak carries a favorable prognosis for HF patients. The results of additional similar investigations, notwithstanding the diverse therapies utilized in those research, supported this. In a clinical study of patients with ischemic heart disease, an increase in VO2peak by 1ml/kg/min was associated with a 14–16% reduction in the risk of mortality.9In the current study, the change in VO2peak from baseline to day 90 of follow-up was substantial, increasing by about 50%.This suggests that people with HF have a lower risk of mortality. The significantly improved quality of life following HFRT was a result of considerable improvements in sleep quality, memory function, and daily routine.

The four components of the HFRT therapy—Snehana, Swedana, Hrudaydhara, and Basti—act primarily in concert to lessen the negative symptoms of CHF. Snehana helps in soothing the patient

through its anxiolytic action. Swedana lowers the preload on the heart by lowering the salt and water burden. Hrudaydhara, a kind of Shirodhara, soothes the patient and lowers blood pressure. In Basti treatment, Terminalia arjuna aids in lowering blood pressure, which lowers the afterload on the heart.10Increasing morbidity and death are linked to increased BMI and ABG in HF patients. After 90 days of HFRT, there was a significant decrease in BMI and ABG, which indicates a better prognosis for HF patients' risk of mortality.11

The gluten-free diet plan helps to reduce blood sugar levels and reduces insulin resistance. It also helps to reduce fat deposition in the liver. It has helped to reduce the weight by 4kg per month.

The key issues with allopathic medicines are the rising cost of therapy and the rising incidence of negative effects associated with their use.12We assessed how HFRT affected reliance on conventional medications in light of this. Our recent investigation showed that patients' dependence on conventional medications had generally lessened after the research time.

Despite the fact that the current study produced a number of significant positive findings, more research of this type-possibly a prospective head-to-head comparative clinical trialis required before the results can be applied to a larger population.

CONCLUSION

According to the results of our study, HFRTalong witha 1200Kcal diet plan and fluid restriction is an effective and practical therapeutic choice for patients with HF and a low ejection fraction who want to increase their ejection fraction.A significant increase in EF, VO2peak, and 6MWT along with a decrease in body weight,BMI, and ABG was observed.HFRT presents a compelling case for consideration as an effective therapeutic alternative for the treatment of HF with low EF.

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.

ETHICS APPROVAL: 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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