

“EFFECT OF THE SAMPURNA HRIDAY SHUDDHIKARAN (SHS) MODEL IN HEART FAILURE PATIENTS IN INDIA: A PROSPECTIVE STUDY”

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ABSTRACT:

Background and Objectives: At present there is no economical treatment available for cardiac failure. However Ayurvedic may provide promising & beneficial treatment for cardiac failure. But unfortunately there is no promising report that shows Ayurvedic is effective treatment for chronic heart failure. In that context we planned present study with objective of the study was to evaluate the effect of the **Sampurna Hriday Shuddhikaran** (SHS) model in improving the exercise tolerance capacity & left ventricular (LV) structure and function in patients with heart failure.

Methods: A prospective observational study with novel noninvasive intervention SHS combines the 4 pronged interventions of Snehana (oil massage to reduce vascular tone & increase venous return), Swedan & Hrid Dhara (thermal therapy to reduce salt & water retention and causing vasodilatation Reduce workload on heart, improves local blood supply & spasm of chest muscles) and Basti (rectal herb to increase cardiac contractility) was used in each patient who received twice daily sessions of 90 mins each for 6 consecutive days.

Results:

Preintervention mean of 6 MWT in meters was 395.47 ± 93.3 & after intervention 510.27 ± 123.3 found to be highly significant ($p < 0.001$) Preintervention mean Ejection fractions was 39.4 ± 14.6 & after intervention 45.9 ± 13.6 found to highly significant ($p < 0.001$). Preintervention mean LV mass index was 129.9 ± 47.7 , IVS was 9.28 ± 2.8 & PWD was 23.6 ± 20.1 . Post intervention mean LV mass index was 138.3 ± 48.8 , IVS was 9.73 ± 3 & PWD was 34.1 ± 27 . The difference was found to be statistically significant after intervention ($p < 0.05$).

Conclusion:

SHS result in an increase in exercise tolerance & ejection fraction (EF). Thus, improving cardiac remodeling and LV systolic function in patients with heart failure.

Keywords: Heart failure, Sampurna Hriday Shuddhikaran, 6 minute walk test, Echocardiography ejection fraction.

1. BACKGROUND& OBJECTIVES:

The definition of heart failure has been variable but as per American Heart Association (AHA) guidelines, HF is a complex clinical syndrome that can result from any structural or functional cardiac disorder which impairs the ability of the ventricle to fill with or eject blood. In 2000, there were an estimated 30 million people with coronary heart disease (CHD) alone in India, or a nearly 3% prevalence [1,2]. The annual incidence of HF for patients with CHD ranges from 0.4% to 2.3% per year [3,4], suggesting that 120 000–690 000 Indians could develop symptomatic HF due to CHD every year. At 40 years of age, the lifetime risk of developing HF, regardless of gender, is one in five, with an incidence of 10 per 1,000 population after the age of 65 years.[5,6] After 5 years, the total number of HF patients accrued could range from 600 000 to 3.5 million; with an estimated 50% mortality at 5 years,[7] The prevalence of other risk factors of HF is also rising in India.

Eighty per cent of total deaths due to non-communicable diseases occur in the low income countries. Men and women are equally affected. Cancer, cardiovascular diseases (CVD) and diabetes are becoming of serious concern, accounting for 52 per cent of deaths and 38 per cent of disease burden in the WHO South East Asia Region (SEAR). With the current trends, the top five causes of disability adjusted life years (DALYs) lost in 2020 are likely to be ischaemic heart disease, unipolar major depression, road traffic injuries, cerebro-vascular diseases, and chronic obstructive lung disease [8]. It has been estimated that a 2 per cent reduction in chronic diseases death rates per year globally could result in saving about 36 million premature deaths by the year 2015 [9] . In addition to the ageing population described above, the prevalence of hypertension is projected to increase from 118 million (2000) to 214 million (2025) [10]. The annual incidence of HF due to obesity (body mass index [BMI] >30 kg/m²) has been estimated to increase by 0.3% in women and 0.5% in men, in the Framingham Heart Study, after adjustment for age, hypertension, left ventricular hypertrophy, myocardial infarction, valve disease, diabetes and cholesterol [11]. . Reddy *et al.* estimated the prevalence of obesity (BMI >30 kg/m²) in 10 970 participants from urban Delhi and rural Haryana in 2002 to be 6.8%. [12] Using these estimates as a benchmark, a 5% prevalence of obesity (BMI >30 kg/m²) in India would lead to an estimated 180 000–300 000 cases of HF annually. Similarly, the prevalence of diabetes in India is projected to increase from 32 million (2000) to 70 million (2025).[13]

The unfinished, pre-transition agenda that bookends India's double burden of disease includes a relatively high prevalence of pretransition diseases, limited healthcare infrastructure, and health disparities, which disproportionately affect people from lower socioeconomic classes and potentially exacerbate disparities further. Since patients have uneven and limited access to healthcare in India, the healthcare infrastructure itself may play a role in the rising burden of HF[14]. The public healthcare system is often overloaded, which makes access to basic services difficult.

India has <2% penetration of health insurance, making the out-of-pocket costs for prevention of HF relatively expensive [15]. Emergency services are not widely available in India, such that patients who experience acute cardiac events, such as acute coronary syndrome (ACS), typically have longer symptom-to-door and door-to-needle times than in other countries.[16]. The combination of inaccessibility, unaffordable treatment and treatment delay possibly increases the incidence of HF in India. Xavier and colleagues evaluated the association between ACS care and socioeconomic status (SES) in the India-based CREATE ACS registry.[17] Patients with a lower SES were less likely to undergo coronary angiography, percutaneous coronary intervention, and coronary artery bypass graft surgery and were less likely to receive medications for secondary prevention of CHD. These disparities contributed significantly to the 2.7% absolute increase in 30-day mortality seen in the poorest stratum compared with that in the richest stratum. However, these differences in mortality were abolished after adjusting for risk factors of CHD, location of infarct, and treatments, suggesting that uniform distribution of CHD and treatment of risk factors of CHD offers an opportunity to improve care. Important social determinants of health such as poverty, lack of empowerment, and healthcare inequalities impede these efforts and are likely to exacerbate the burden of HF in India.

At present there is no economical treatment available for cardiac failure. However Ayurvedic may provide promising & beneficial treatment for cardiac failure. But unfortunately there is no promising report that shows Ayurvedic is effective treatment for chronic heart failure. Reviewing the clinical researches in Ayurveda is found intertwined with huge difficulties primarily because of unavailability of qualitative research works which are published and accessible. In that context we planned to study the effect of the Sampurna Hriday Shuddhikaran (SHS) model in improving the exercise tolerance capacity of chronic heart failure patients.

The objective of the study was to evaluate the effect of the Sampurna Hriday Shuddhikaran (SHS) model in improving the exercise tolerance capacity & left ventricular (LV) structure and function in patients with heart failure.

2. METHODS

The study was a prospective observational study. All patients provided written informed consent and the study was approved by the Institutional ethical committee on medical research ethics. Patients were recruited as outpatients by a single centre. Symptomatic patients (age 33 – 80 yrs) with CHF (Grade 1-3 of NYHA classification), of either gender, with ejection fraction more than 25%. were included in study. Patients with history of Myocardial infarction in last 2 weeks, uncontrollable hypertension (SBP $\geq$ 180 & DBP $\geq$ 110 mmHg), severe hepatic/renal insufficiency, pregnancy/lactating were excluded.

2.1 Interventions: four weeks of treatment with Sampurna Hriday Shuddhikaran (SHS) .

- 110 Novel noninvasive interventional health Sampurna Hriday Shuddhikaran (SHS) procedure was used to
 111 treat CHF patients.
- 112 SHS combines the 4 pronged interventions.

INTERVENTION PROCEDURE	METHOD	RATIONALE
1.SNEHAN	A til oil centripetal massage in strokes directed toward the heart.	→Reduce vascular Tone →Increase venous return
2.SWEDAN	An herbal moist steam bath to the whole body below the neck, using about 50 g of <i>Terminalia arjuna</i> bark.	→Reduce salt and water retention →Reduce workload on heart
3.HRID DHARA	We concentrated an herbal decoction of 50 g of <i>T. arjuna</i> bark on the precordial area.	→Improves local blood supply & spasm of chest muscles
4.BASTI	An herbal enema given very slowly using decoction of 10 g of <i>T. arjuna</i> bark ^[9] . The decoction was prepared in 1000 ml of water that was boiled until the water evaporated to 100 ml. This was administered rectally. Twice daily sessions of 90 mins each for 6 consecutive days.	→Increases Cardiac Contractility

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114 **2.1.1 Clinical assessment**

1. Exercise Tolerance capacity [as measured by standard 6 minute walk test (6MWT);

"The 6MWT is a useful measure of **functional capacity** targeted at people with at least moderately severe impairment. The test has been widely used for preoperative and postoperative evaluation and for measuring the response to therapeutic interventions for cardiac disease." [18].

The 6MWT has been used in many studies to assess the effect of therapeutic interventions in patients with heart failure. The variations in the distance walked during the walking test have been reported to identify the short term effects of the tailoring of standard pharmacological therapy (diuretics, vasodilators, digitalis) and of a personalized program of physical training [19, 20, 21, 22]

The walking test was performed in an indoor unobstructed 60-m long corridor, according to the recommendations of Guyatt et al. [23] and the American Thoracic Society [24]. All patients were informed in a standardized manner of the purpose and method of the test before the test was performed. They were instructed to walk the corridor from one end to the other at their own pace, as many times as possible, in the permitted time. The patients were advised on the possibility of slowing down the pace and stopping or resting as needed to resume walking as soon as they felt they were able to do so. After 6 min had elapsed, patients were instructed to stop walking, and the total distance walked was measured. The test was supervised by a physical therapist who encouraged the patients in a standardized fashion at regular intervals. A baseline 6MWT was performed within 24 h of hospital admission or once symptoms at rest had subsided and fluid retention had resolved, and a second test was performed at discharge.

2 D Echocardiogram:

Echocardiography, according to ACC / AHA guidelines on HF is " the single most useful diagnostic testing in the evaluation of HF because of its ability to accurately and non invasively provide measures of ventricular function and assess causes of structural heart disease" [25]

A two-dimensional (2D) Doppler echocardiogram is used to check the size of the heart's chambers, the function of the heart valves, the size and movement of the heart muscle wall, and the pattern of blood flow through the heart. Because the test can measure how much blood is flowing in and out of the chambers of the heart, the echo is used to determine a common measure of heart function called the ejection fraction, the percentage of blood pumped out of the heart during each heartbeat. [26] A standard protocol was used, based on apical two and four chamber views according to the recommendations of the American Society of Echocardiography. [27]

The aims of the echocardiographic examination were to evaluate the effect of SHS on left ventricular mass index, Posterior wall diameter, left ventricular internal diastolic diameter (LVIDd) and EF. In this we had looked for any irregularities in the size and movement of heart, size of the heart chambers and the thickness of the muscle wall. A thicker heart muscle wall may mean your heart's ability to relax and fill

with blood is impaired (blood-filling problem). A stretched (dilated) heart muscle wall may indicate a weakening heart. The test will show if the muscle wall is moving properly, contracting (squeezing) to pump out enough blood to meet the body's needs and then relaxing to refill with enough blood.

2.1.1.1 Statistical analysis

Data were entered on and analyzed using the SPSS-16.0 statistical package .Change in six minute walking distance and 2 D echo parameter were normally distributed and analyzed using two sample Student's *t* test.

3. RESULTS:

Out of total 133 majority of the study subjects were in age group between 53 to 62 years of age(34.6%) followed by 63 to 72 years.(30.8%). Mean age of the study participant was 58.38 ± 1.03 . 107 (80.5%) were male while 26(19.5%) were female.(Table-1)

Table 1. Sociodemographic characteristics of study sample by Age & Sex.

Characteristics	Number of participants
Age in years	N=133
33—42	11(8.3)
43—52	25(18.8)
53—62	46(34.6)
63—72	41(30.8)
73—82	10(7.5)
Sex	
Male	107(80.5)
Female	26(19.5)

Figures in parenthesis indicate percentage.

Mean age : 58.38 ± 1.03

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164 50.4% was found to be normal BMI (18.5—24.99 kg/m²) & 44.4% was overweight (BMI > 25 kg/m²)

165 .The Mean BMI (kg/m²) was 24.52± 3.89.(table-2)

166 **Table 2 : Body mass index (BMI) of study participants :**

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BMI (kg/m ²)	No
< 18.5	7(5.3)
18.5—24.99	67(50.4)
25 & above	59(44.4)

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Figures in parenthesis indicate percentage.

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Mean BMI =24.52± 3.89

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171 Preintervention mean of 6 MWT in meters was 395.47±93.3 & after intervention mean of 6 MWT in

172 meters was 510.27 ±123.3 .It was found to be highly significant (p<0.001) & There was strong

173 correlation between two parameter (r=0.35).

174 Preintervention mean Ejection fractions was 39.4± 14.6 & after intervention mean EF was 45.9±13.6. It

175 was found to highly significant (p< 0.001) & there was significant correlation (r=0.847). (Table 3)

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	Variables	n	Mean	SD	SE	r	P
Pair 1	Six minute walk test (in meters)	133	395.47	93.37	10.78	0.357	<0.001
	before intervention & Six minute	133	510.27	123.44	14.25	SC	HS

188 **Table 3: Pre & Post Intervention 6 MWT & 2 D Echo findings in Study Participants:**

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	walk test (in meters) after intervention)						
Pair 2	EF (before intervention & After intervention)	133 133	39.43 45.98	14.69 13.69	1.27 1.18	0.847 SC	<0.001 HS
Pair 3	LV mass index (before intervention & After intervention)	133 133	129.98 138.33	47.74 48.8	4.14 4.23	0.559 SC	<0.05 S
Pair 4	IVS (before intervention & After intervention)	133 133	9.28 9.73	2.83 3.08	0.244 0.267	0.646 SC	<0.05 S
Pair 5	PWD (before intervention & After intervention)	133 133	23.66 34.18	20.19 27.08	1.75 2.34	0.052 NSC	<0.001 HS

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192 SC: significant correlation

HS : highly significant

193 NSC: No significant correlation

S : significant

194 NS : Not Significant

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197 Despite several other methods, ejection fraction (EF) continues to be the gold standard for clinicians.

198 This is the most common indication for performing echo & it has a significant prognostic value. The new

199 American Society of Echocardiography guidelines define an abnormal EF < 55%, with the cut off's for

200 moderately abnormal and severely abnormal at 44% and 30% respectively.

201 Preintervention mean LV mass index was 129.9±47.7, IVS was 9.28±2.8 & PWD was 23.6±20.1

202 respectively. Post intervention mean LV mass index was 138.3±48.8, IVS was 9.73±3 & PWD was

203 34.1±27. The difference was found to be statistically significant after intervention (p= 0.05).

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205 **4. DISCUSSION:**

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208 The most important result of this study is that SHS showed a significant improvement in exercise
209 tolerance and able to partially reverse eccentric remodeling, (LV mass and LV volumes) in 133 patients
210 with heart failure following a 4-week intervention. Because all of the patients were studied
211 echocardiographically, the relationship between outcomes and LV structure and function was confirmed.
212 Comparison of the preintervention & postintervention in study participants at day 1 & day 30 showed an
213 increase in mean of 6 MWT in meters (395.47±93.3 vs. 510.27 ±123.3 $P<0.001$ & $r=0.35$) Our outcomes
214 were consistent with previous research studies involving outpatient intervention programs designed to
215 increase the functional capacity.[28]

216
217 However, one observational study similar to ours study found equal improvements between individuals
218 with and without left ventricular dysfunction in the six-minute walk distance and quality of life scores [29].
219 Lower levels of functional capacity (a distance <300 m during 6MWT) have proven to be predictive of
220 mortality (total or cardiovascular) and morbidity (hospitalization for worsening heart failure) both in
221 patients with mild-moderate [30,31,32] and advanced heart failure [33,34]. In the SOLVD study, total
222 mortality was 10.23% in subjects with a 6MWT<300 m and 2.99% in subjects with a 6MWT≥450 m [30].

223 SHS improves hemodynamic conditions: ejection fraction (EF) increases after four week Intervention (
224 39.4±, 14.6 & 45.9±13.6.) It was found to highly significant ($p< 0.001$) & significant correlation ($r=0.847$). .

225 Comparison of the carvedilol group at 4 and at 12 months showed an increase in EF (28.0±7.3 vs.
226 34.9±7.7 $P<0.01$) In a different study, Arjuna extract reversed heart failure from NYHA VI to NYHA I, and
227 showed significant improvement in ejection fraction and reduction in the left ventricular muscle size in a
228 double blind study of patients with congestive heart failure, showed significant improvement of left
229 ventricular ejection fraction (35.33 +/- 7.85 vs. 30.24 +/- 7.13%; $P < 0.005$).and decrease in heart size.
230 Reduced cardiac associated symptoms including dyspnoea, fatigue, oedema and walking tolerance
231 improved. Terminalia was taken concomitantly with standard heart medication. [35].
232

233 The significant difference was found between Preintervention mean LV mass index, IVS & PWD &
234 Postintervention mean LV mass index, IVS & PWD. ($p=0.05$). The improvement in exercise tolerance &
235 echocardiographic findings in the current study confirms the beneficial action of SHS in heart failure
236 patients; the exact mechanism cannot be explained on the basis of positive geometrical reverse.
237 Such studies are necessary and serve as an important indication that individuals with CHF can safely
238 benefit from cardiac rehabilitation programming while learning lifestyle modifications that may improve
239 overall health. Although there may never be complete restoration of pre-disease physical functioning
240 levels in individuals with CHF, these initial increases, if sustained, may be meaningful in terms of the
241 quality of a potentially prolonged life span.

242 4.1 LIMITATION OF STUDY:

243 A limitation of this study is the lack of a control group for comparison to treatment withheld.

244 5. CONCLUSIONS:

245 Six minute walking distance is improved considerably by Auurvedic treatment with SHS in patients with
246 heart failure. Also SHS had a favorable effect on outcome result in an increase in ejection fraction (EF) or
247 a reduction in left ventricular (LV) dimension. This favorable effect on LV chamber size and function has
248 been attributed to regression of structural remodeling.

249 Currently, we are examining if these short-term outcomes can be sustained for a longer period of time in
250 the individuals with Heart Failure. In addition, hospital-based cardiac rehabilitation programs may also
251 find they can increase program revenue by safely integrating individuals with Heart Failure into their
252 maintenance programs.

253 The benefit on outcome in SHS was accompanied by echocardiographic evidence for regression of LV
254 remodeling. The study results further illustrate the usefulness of monitoring structural changes in the left
255 ventricle as a guide to long-term efficacy in heart failure treatment.

256 CONSENT:

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258 All authors declare that 'written informed consent were obtained from the patients
259 for publication of this research work.

260 ETHICAL APPROVAL

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262 All authors hereby declare that all experiments have been examined and approved by the
263 Institutional ethics committee and have therefore been performed in accordance with the
264 ethical standards laid down in the 1964 Declaration of Helsinki.

265

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270

271 COMPETING INTERESTS

272 Authors have declared that no competing interests exist.

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