

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

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7 **ABSTRACT:**
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9 **Background and Objectives:** Chronic heart failure (CHF) is an increasingly widespread, costly
10 and deadly disease, frequently named as an epidemic of the 21st century. Herbal treatments
11 may provide promising & beneficial treatment for heart failure. But unfortunately there is no
12 promising report that shows herbal treatment is effective treatment for chronic heart failure. In
13 that context we planned present study. **The objective** of the study was to evaluate the effect of
14 the **herbal procedure** Sampurna Hriday Shuddhikaran (SHS) model in improving **the left**
15 **ventricular (LV) structure & function and exercise tolerance capacity in patients with heart**
16 **failure.**

17 **Methods:** 133 patients (107 male & 26 Female) were selected for study. A prospective
18 **interventional** study with novel noninvasive intervention **SHS consist of the 4 pronged**
19 **interventions of Snehana, Swedan, Hrid Dhara and Basti** was used in each patient who received
20 twice daily sessions of 90 mins each for 6 consecutive days. **Preintervention 2 D echo & 6**
21 **minute walk test in meters were done on first day of admission. Postintervention 2 D echo & 6**
22 **MWT were done after 30 days and 6 days respectively.**

23 **Results:**

Preintervention mean Ejection fractions was 39 ± 14.6 & after intervention ejection fraction was 45 ± 13.6 . This difference was found to be highly significant ($p < 0.001$). Preintervention Interventricular septum (IVS) was 9.2 ± 2.8 & Post intervention IVS was 9.7 ± 3 ($p < 0.05$). Preintervention mean of 6 MWT in meters was 395 ± 93.3 & after intervention 510 ± 123.3 found to be highly significant ($p < 0.001$).

Conclusion:

Herbal treatment procedure SHS is associated with improvements in ejection fraction myocardial thickness and exercise tolerance.

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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 leading to disability adjusted life years (DALYs). 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.

Herbal treatment may provide promising & beneficial treatment for heart failure. But unfortunately there is no promising report that shows herbal treatment is effective treatment for chronic heart failure. Reviewing the clinical researches in herbal treatment 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 herbal procedure 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 left ventricular (LV) structure, function and exercise tolerance capacity in patients with heart failure.

2. METHODS

The study was a prospective interventional 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 inpatients by a single centre at Madhavbaug hospital. Symptomatic patients (age 33 – 80 yrs) with CHF (Grade 2-3 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. The patients was kept in hospital for 6 days after which he gets discharged.

Expert persons performing 2 D echo & 6 MWT were blinded & following protocol was followed for study participants:

0 Day - Admission and 2 D echo testing & 6 Minute walk test measured in meters

0 to 6th day - Two sessions of SHS were performed everyday for 6 consecutive days

74 6th day – 6 Minute walk test & discharge

75 30th day- 2 D echo testing

76

77 2.1 INTERVENTION:

78 A single session of novel noninvasive interventional herbal procedure, Sampurna Hriday Shuddhikaran
79 (SHS) is of 90 minutes duration. Two sessions of SHS were performed everyday for 6 consecutive days
80 to treat CHF patients. There was no other intervention received by patients during their hospital stay of 6
81 days.

82 SHS consists of the 4 pronged interventions in following order.

83 **1.SNEHAN:** A til oil centripetal massage in strokes directed toward the heart from periphery. **2.SWEDAN:**
84 Patient lies in a closed wooden chamber with head remains outside the chamber. An herbal moist steam
85 bath to the whole body below the neck, using about 50 g of *Terminalia arjuna* bark. This procedure leads
86 to profuse body sweating. **3.HRID DHARA:** Patients chest is packed with dough. Warm herbal decoction
87 of 50 g of *T. arjuna* bark is made to concentrate on the precordial area. **4.BASTI:** An herbal enema given
88 very slowly using decoction of 10 g of *T. arjuna* bark. The decoction was prepared in 1000 ml of water
89 that was boiled until the water evaporated to 100 ml. This was administered rectally.

90 2.1.1 CLINICAL ASSESSMENT

91 1. 2 D Echocardiogram:

92 The aims of the echocardiography examination were to evaluate the effect of SHS on interventricular
93 septum and EF. 2 D echo parameters were measured by M-mode as per guidelines of American Society
94 of Echocardiography (ASE) using standard protocol based on apical two and four chamber views.
95 Parameters measured were ejection fraction in % & thickness of interventricular septum in mm. 2 D echo
96 testing was done first on day 1 on admission & second was done after 30days by same qualified
97 person.

98

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

100 The 6MWT has been used in many studies to assess the effect of therapeutic interventions in patients
101 with heart failure. [13] After 6 min had elapsed, patients were instructed to stop walking, and the total
102 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 on the first day of admission before treatment and on the 6th day on which patients get discharged after treatment. Patients were called after 30 days for 2 D echo testing.

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 paired *t* test. Post study statistical power of the test was found to be 96.38 %.

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.

119 Mean age: 58.38± (SD 1.03)

120

121 50.4% was found to be normal BMI (18.5—24.99 kg/m2) & 44.4% was overweight (BMI > 25 kg/m2)

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

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

124

BMI (kg/m2)	No
< 18.5	7(5.3)
18.5—24.99	67(50.4)
25 & above	59(44.4)

125 Figures in parenthesis indicate percentage.

126 Mean BMI =24.52 ± 3.89

127

128 Preintervention mean Ejection fractions (%) was 39.4± 14.6 & after intervention mean EF (%) was 45.9 ±
129 13.6. It was found to highly significant ($P < 0.001$). Preintervention IVS (in mm) 9.28 ± 2.8 and Post
130 intervention IVS 9.73 ± 3 ($P = 0.05$) (Table 3).

131 Preintervention mean of 6 MWT in meters was 395.47 ± 93.3 & after intervention mean of 6 MWT in
132 meters was 510.27 ± 123.3 .It was found to be highly significant ($P < 0.001$)

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

Pair	Row No.	Variables	N	Mean	SD	SE	P value
Pair 1	1	EF (before intervention)	133	39.43	14.69	1.27	<0.001 HS
	2	EF (After intervention)	133	45.98	13.69	1.18	
Pair	3	IVS before intervention	133	9.28	2.83	0.244	<0.05

2	4	IVS after intervention	133	9.73	3.08	0.267	S
Pair	5	Six minute walk test (in meters) before intervention	133	395.47	93.37	10.78	<0.001 HS
3	6	Six minute walk test (in meters) After intervention	133	510.27	123.44	14.25	

Rows 1,3,5 represents before intervention values & Rows 2,4,6 represents after intervention values.

HS : highly significant S : significant

4. DISCUSSION:

The most important result of this study is that 6 days of SHS intervention showed a significant improvement in echocardiography parameters as well as exercise tolerance in 133 patients with heart failure. Because all of the patients were studied echocardiographically, the relationship between outcomes and LV structure and function was confirmed.

SHS improves hemodynamic conditions as ejection fraction (EF) increases after 6 days of Intervention by 6.5 % (39 ± 14.6 & 45 ± 13.6 .) This difference was found highly significant ($p < 0.001$). Also thickness of interventricular septum was improved significantly from 9.2 mm to 9.7mm.

Comparison of the preintervention & postintervention in study participants at day 1 & day 6 showed an increase in mean 6 MWT of 115 meters (395 ± 93.3 vs. 510 ± 123.3 $P < 0.001$) Our outcomes were consistent with previous research studies involving outpatient intervention programs designed to increase the functional capacity.[23]

However, one observational study similar to ours study found equal improvements between individuals with and without left ventricular dysfunction in the six-minute walk distance and quality of life scores [24]. Lower levels of functional capacity (a distance < 300 m during 6MWT) have proven to be predictive of mortality (total or cardiovascular) and morbidity (hospitalization for worsening heart failure) both in patients with mild-moderate [25,26,27] and advanced heart failure [28,29]. In the SOLVD study, total mortality was 10.23% in subjects with a 6MWT < 300 m and 2.99% in subjects with a 6MWT ≥ 450 m [25].

The improvement in echocardiographic & exercise tolerance findings in the current study is associated with SHS intervention in heart failure patients.

Such studies are necessary and serve as an important indication that individuals with CHF can safely benefit from cardiac rehabilitation programming while learning lifestyle modifications that may improve overall health. *Although there may never be complete restoration of pre-disease physical functioning levels in individuals with CHF, these initial increases, if sustained, may be meaningful in terms of the quality of a potentially prolonged life span.*

4.1 LIMITATION OF STUDY:

A limitation of this study is the lack of a control group for comparison to treatment withheld and long term follow up parameters is difficult & needs patients cooperation.

5. CONCLUSIONS:

Herbal treatment procedure SHS is associated with improvements in ejection fraction , myocardial thickness and effort tolerance capacity in patients with heart failure in just 6 days. *The study results further illustrate the usefulness of monitoring structural changes in the left ventricle as a guide to long-term efficacy in heart failure treatment.*

CONSENT:

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

ETHICAL APPROVAL

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

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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