

## INDIAN COUNCIL OF MEDICAL RESEARCH

### FORMAT FOR ANNUAL PROGRESS REPORT

1. Title of research project: **Comprehensive Heart Failure Program**

Location: SreeChitraTirunal Institute for Medical Sciences and

Technology, Trivandrum, India.

Postal address – Medical College PO, Trivandrum- 695011.

Telephone -0471-2443152

2. Name and Designation of the Chief Investigator:

Dr.Harikrishnan.S

Additional Professor, Department of Cardiology,

SreeChitraTirunal Institute for Medical Sciences and

Technology, Trivandrum, India.

Medical College PO, Trivandrum- 695011.

3. Date of starting: 16/07/2012

4. Expected duration: 3 Years

5. Highlight briefly the findings : See attached report

6. Detailed report of work done on the project from the date of last submission of the report\*: Attached

7. Period covered by the present report from: 19/03/2014 to 15/01/2015

8. Programme of work proposed to be\* : See the attached report  
Undertaken during the next year.

9. List of papers published on the :  
basis of work done on the research  
Project during the year. Reprint  
of each of the paper published:

Harikrishnan Sivadasanpillai, Sanjay Ganapathy, C.G. Bahuleyan, D. Dalus, Madhu Sreedharan, Rao Asok Chandra, Sunitha Viswanathan, Suresh Krishnan, Tiny Nair, Vijayaraghavan Govindan. Clinical Presentation, Management, And In-Hospital Outcomes Of Patients Admitted With Decompensated Heart Failure In Trivandrum, Kerala, India. GLOBAL HEART - March 2014 Volume 9, Issue 1, Supplement, Page e57

**10. Any other salient features:**

1. Based on the work related to the Trivandrum Heart Failure Registry, the PI, Dr Harikrishnan.S was selected as the International and regional topic group leader in Heart failure along with David Kaye of Australia and Karen Sliwa of South Africa in the prestigious World Congress of Cardiology, organised by the World Heart Federation, in Melbourne, Australia, May 4-7, 2014.
2. Based on the abstract on Trivandrum Heart Failure registry, the PI, Dr Harikrishnan.S was invited to give a podium presentation on **Heart Failure in India** at the prestigious World Congress of Cardiology, organised by the World Heart Federation, in Melbourne, Australia, May 4-7, 2014. (Program schedule attached.)

**ENCLOSURES**

1. Detailed project report
2. Publication arising out and related to the project. (1)
3. Abstract submitted to World Heart Failure Congress organised by the European Society cardiology.
4. Original Research Article submitted to the Journal of American College of Cardiology – Heart Failure and under review.
5. Program Schedule of World Congress of Cardiology by the World Heart Federation.
6. Brochure of the meeting of the Society for heart failure and transplantation.
7. Original utilization certificate from the accounts department of our Institute.

PLACE  
DATE

Signature of the chief Investigator

# REPORT

There are two components for the project. They are:

- 1) Trivandrum Heart Failure registry
- 2) Comprehensive Heart Failure intervention program.

## ***1) Trivandrum heart failure registry.***

For this registry, we had selected two areas in Trivandrum district – one rural and one urban area. The participating hospitals and the respective co-ordinators (PIs) are

### *a. Trivandrum city corporation area – Urban area*

**(Area 141 Sq Km, 7,45,000 Population)**

- 1) Ananthapuri Hospitals and research Institute – Dr CG Bahuleyan
- 2) Cosmopolitan Hospital – Dr Biju R
- 3) Govindan's hospital – Dr K Krishnakumar
- 4) General Hospital, Trivandrum – Dr Jayapal.A
- 5) Jubilee Hospital – Dr BVR Kumar
- 6) Kerala Institute of Medical Sciences – Dr G Vijayaraghavan
- 7) Medical College Hospital, Trivandrum – Cardiology, Dr SunithaViswanathan
- 8) Medical College Hospital, Trivandrum – Medicine - Dr SunithaViswanathan
- 9) Meditrina Hospitals – Dr Pratap Kumar
- 10) PRS hospital- Dr. Tiny Nair
- 11) SK hospital – Dr K Suresh
- 12) SCTIMST – Dr.Harikrishnan.S and (co-PI: Dr Sanjay G & Dr Anees T)
- 13) SUT group of Hospitals – Dr AC Rao.

## **b. Trivandrum – Rural area.**

Athiyannoor block panchayat (Area 42 Sq Km, Population 4.5 Lakhs.)

- 1) NIMS Hospital, Neyyattinkara – Dr MadhuSreedharan
- 2) PHC – Venapakal – Dr SivaKumar. M
- 3) PHC – Pulluvila - Dr Preetha.J
- 4) PHC – Vizhinjam - Dr Mini.S
- 5) Taluk Headquarters hospital, Neyyattinkara– DrSadasivan.S.

All the hospitals with in-patient facility where HF patients are likely to be admitted were invited to participate in the study. We had a very good response and all hospitals agreed to participate in the registry. Twelve hospitals in the urban area and 5 hospitals in the rural area have participated in the registry. All the physicians, cardiologists and general practitioners in the area were part of the study.

The data collection of the registry was completed on December 31, 2014, except from Medical College Trivandrum, department of medicine, where the data collection was completed on March 31<sup>st</sup>, 2014. All the details including demographics, etiology of heart failure, medical history, clinical presentation, in-hospital diagnostics and treatment were captured using the questionnaire.

In 2014, we captured the follow-up data. Even though we intended to capture follow-up data for 3 months, we could capture one year follow-up data. (attached).

**We have collected the data of 1205 patients as part of the Trivandrum Heart Failure Registry.** We expected 700 patients when we planned the registry, but we got 1205 patients. We analysed the 3 month follow-up data and submitted the manuscript to BMJ-HEART, reviewed, but was rejected with comments. We have submitted the manuscript to Journal of the American College of cardiology – Heart Failure (JACC – HF).

The preliminary analysis of the one year follow-up data is attached below. The one year follow-up was done either through their hospital visits or over telephone.

Preliminary analysis shows that the one year mortality is 22.7% ( 265 patients – out of 1170 patients followed up). We are maintaining this cohort and is planning to collect the 2 year follow-up data.

**The data from the Trivandrum Heart Failure Registry – In hospital data, outcomes and 3 month follow-up data. January 2013– March 31 2014.**

***Demographic characteristics***

In total, 1232 patients were admitted in the participating hospitals with the diagnosis of HF during the study period. Patients who were admitted in one hospital and referred to another hospital in the registry (n=27) were excluded. We enrolled 1,205 patients into the registry during the one-year period. Of them 834 (69%) were men, and 371 (31%) were women. Only one tenth of the registered patients (n=128) were from the rural centers. Mean (SD) age of the population was 61.2 (13.7) years. More than half (57%) reported less than primary level education.

***Clinical Characteristics***

Two out of every five patients reported acute de-novo heart failure. The most common etiology was ischemic heart disease (IHD) (72%) followed by dilated cardiomyopathy (13%) and rheumatic heart disease (RHD, 8%). The prevalence of cardiovascular risk factors in the study population were current tobacco use (16%), current alcohol use (19%), hypertension (58%), diabetes (55%), chronic obstructive pulmonary disease (15%), and chronic kidney disease (18%). Majority (85%) of the patients were in sinus rhythm (SR), while atrial flutter or fibrillation was detected in 15% of the patients. Patients with LV ejection fraction more than 45%, (defined as heart failure with preserved ejection fraction) constituted 26% of the population.

***Duration of hospital admission, treatment and in-hospital mortality***

The median duration of hospital stay was 6 days (IQR=4-9 days). Almost all patients (94%) received diuretics during admission, while the proportion of the enrolled patients on beta blockers, ACE inhibitors/ARB were 54% and 46%, respectively (Table 2). Aldosterone blockers were prescribed to 44% of the population. Optimal treatment was given to 19% (95% CI: 16.4-21.6) the patients with LVSD during hospital admission. One third (34%) of the patients underwent coronary angiogram during the hospitalization period. Similarly, one fifth (19%) of the patients underwent percutaneous coronary interventions, and 6% of the patients underwent coronary artery bypass graft surgery. The total in-hospital mortality was 8.5% (n=102, 95% CI: 6.9-10.0). Optimal treatment was prescribed to 25% (95% CI: 21.8-27.4) of the patients with LVSD during hospital discharge.

Table 1: Characteristics of the study population.

<b>Variables</b>	<b>Total (N=1205)</b>
Age in years, mean (SD)	61.23 (13.68)
Women, n (%)	371 (30.79)
Educational status, n (%)	
No education	142 (11.81)
Up to primary	540 (44.93)
Secondary	363 (30.20)
Graduates and above	157 (13.06)
Acute de-novo heart failure	479 (40%)
Etiology, n (%)	
Ischemic heart disease	866 (71.87)
Dilated cardiomyopathy	156 (12.95)
Hypertrophic cardiomyopathy	27 (2.24)
Rheumatic heart disease	95 (7.88)
Hypertension	11 (0.91)
Miscellaneous	50 (4.15)
Tobacco use, n (%)	
Current use	188 (15.60)
Past use	301 (24.98)
Alcohol use, n (%)	
Current use	234 (19.42)
Past use	21 (1.74)
History of hypertension, n (%)	696 (57.76)
History of diabetes, n (%)	662 (54.94)
Atrial fibrillation/Flutter, n (%)	177 (14.69)
History of stroke, n (%)	75 (6.22)
History of COPD, n (%)	186 (15.44)
History of CKD, n (%)	216 (17.93)
Heart rate>100 beats/minute at admission, n (%)	720 (60.05)
NYHA Class IV, n (%)	382 (32.87)
LV ejection fraction<35%, n (%)	544 (45.15)

Table 2: Admission, discharge medications and optimal treatment

Medicines	Overall (1205)		Patients with LVSD (N=894)	
	Admission	Discharge	Admission	Discharge
ACE inhibitors, n (%)	445 (36.93)	465 (38.59)	351 (39.26)	366 (40.94)
Angiotensin receptor blockers, n (%)	110 (9.13)	122 (10.12)	77 (8.61)	83 (9.28)
Beta blockers, n (%)	649 (53.86)	701 (58.17)	500 (55.93)	538 (60.18)
Diuretics, n (%)	1132 (93.94)	983 (81.58)	848 (94.85)	737 (82.44)
Aldosterone receptor anatgonists, n (%)	527 (43.73)	553 (45.89)	421 (47.09)	443 (49.55)
Vasodilators, n (%)	396 (32.86)	316 (26.22)	290 (32.44)	233 (23.06)
Digoxin, n (%)	374 (31.04)	337 (27.97)	291 (32.55)	257 (28.75)
Heparin, n (%)	512 (42.49)	154 (12.78)	380 (42.51)	93 (10.40)
Inotropic agents, n (%)	129 (10.71)	2 (0.17)	99 (11.07)	1 (0.11)
Optimal treatment, n (%)	203 (16.85)	258 (21.41)	170 (19.02)	220 (24.61)

### ***Three months follow-up data and survival analyses***

The 90-day follow-up rate was 97%, and 35 patients were lost to follow-up after discharge from the hospital. The total time at risk was 85,701 person days with a median follow-up period of 85 days. The 90-day all-cause mortality rate was 2.43 deaths per 1000 person days of follow-up (95% CI: 2.11-2.78) (Table 3).

In the Kaplan-Meier (KM) mortality curves for optimal treatment (Figure 1A-1D), those who did not receive optimal treatment reported significantly shorter survival time and higher mortality than those who received optimal therapy ( $p < 0.001$ ). Consistent results were seen in the total population (Figures 1A-1B) and in individuals with LVSD (Figures 1C-1D). In the multi-variate Cox-PH model, the variables associated with mortality were optimal in-hospital treatment (HR=0.28, 95% CI: 0.14-0.53), age>55 years (HR=1.50, 95% CI: 1.05-2.15), LVEF>35% (HR=0.71, 95% CI: 0.52-0.95), NYHA class IV (HR=1.60, 95% CI: 1.18-2.16) and below primary educational status (HR=1.82, 95% CI:1.04-3.17) (Figure 2). No violation in the proportionality hazard assumption was detected. The model with the above mentioned variables predicted nearly 72% variation on mortality in the study population (AUC ROC=0.72, 95% CI: 0.68-0.76) (Figure 3).

Table 3: In-hospital admission, mortality, follow-up duration and 3 months mortality

<b>Variables</b>	<b>Men (n=834)</b>	<b>Women (n=371)</b>	<b>Total (N=1205)</b>
Duration of stay, median (IQR)	6 (4-9)	6 (4-9)	6 (4-9)
In-hospital mortality, n (%)	65 (7.79)	37 (9.97)	102 (8.46)
Time at risk, person days of follow-up	59214	26487	85701
Follow-up days, Median	85	84	85
Total mortality rate, n (%), rate per 1000 person days of follow-up)	140 (16.79, 2.36)	68 (18.33, 2.6)	208 (17.26, 2.43)

## II) COMPREHENSIVE HF INTERVENTION PROGRAM

This is the second component of the project. Our hospital SCTIMST has started a Heart Failure program which was initiated with the inauguration of HF clinic on January 1, 2012. The HF clinic continued to function this year also.

### ***Heart Failure Clinic.***

We have established the first comprehensive heart failure clinic in governmental sector in the country. The HF clinic is on all Wednesdays from morning till evening. A new room with a size of 150 Sq feet was allotted to the HF clinic by the hospital administration and the clinic is being run in this new area. Another room 150 sq Ft is allotted for the expansion of the clinic and will be functioning as part of the clinic from February 1, 2014.



**Figure 1: Newly initiated dedicated Heart Failure Clinic**

20-25 patients with HF of varying aetiologies attend each clinic regularly. Two cardiologists are dedicated to this clinic. About 400 patients attended the clinic in the last one year, and are on regular follow-up.

We have streamlined the management of HF patients suited to our country and our patient population and the quality of life (QOL) as assessed by the QOL questionnaire has improved once the clinic has started functioning.

The process to purchase an Echocardiography equipment to be used in the HF Clinic was initiated in July 2012, and the Echocardiography machine (PHILIPS HD 11 XE Color Doppler echocardiography equipment) was installed in 2014. With the addition of the Echocardiography facility in the clinic, the functioning of the HF clinic has become smoother as there is no need to transfer patients to the main block of the hospital for echocardiography evaluation.



**Figure 2: Philips HD 11 XE Color Doppler Echocardiography equipment inducted into the Heart Failure Clinic.**

#### **PSYCHIATRY CLINIC AND COUNSELLING.**

Patients with HF are sick and they have psychological issues and stress. Our hospital has signed an MOU with the Department of Psychiatry, Government Medical College, Trivandrum to have a research and clinical collaboration in evaluating and treating psychological and psychiatric morbidity in patients with HF.

As part of the collaboration, one faculty from the Department of Psychiatry is attending the HF Clinic every week and provides clinical services and also counselling to those patients who need them.

The next step is to initiate a research program to evaluate the psychiatric and psychological morbidity in Indian patients with HF and to develop India specific tools in local Language – Malayalam to capture the morbidity. The proposal is being developed.

### **HEART FAILURE REHABILITATION PROGRAM**

With collaboration from the Department of Physiatry, we are starting a HF rehabilitation program. A Treadmill exercise machine is being purchased to aid in the rehab program. The services of the dietician from the Dietary department of our hospital is used to provide dietary and nutritional counselling.

### **Heart Failure ICU and Wards.**

Currently the HF patients are being managed in the existing ICUs and the wards of the cardiology department.

As part of the HF program, the Institute is starting a Heart failure ICU and ward in the Medical block. The facility is planned to have 9 beds equipped with state-of the art monitoring and treatment facilities. The facility will have an area of 400 Sq feet and the approximate cost of the program is 2.1 Crores INR. The floor plan of the proposed heart failure ICU is attached. Almost all the equipments required for the Heart Failure ICU have been purchased and stored. The air-conditioning works are tendered and the civil works will be initiated in March 2015. The full-fledged HF ICU is expected to function towards the end of 2015. The necessary civil modifications in the adjacent wards have been completed.

### **Staff**

Five staff nurses joined in the project in December 2012 and the data-entry operator and Research Assistant also joined in the same period. One staff nurse is looking after the

heart failure OPD and also collecting the follow-up data from the Heart Failure registry. **Five** of the staff nurses are posted in the HF ward and ICU.

Since the project has approval from ICMR only till March 19, 2015, we could give extension for the existing staff only till that date. Some of the staff nurses have left the project in between as it is a temporary assignment. We are requesting for an extension (**no cost**) of the project for six more months as some funds are remaining unutilised.

## **ACTIVITIES RELATED TO THE PROJECT**

### **1. Annual meeting of the Society for Heart Failure and Transplantation, India -2014.**

We hosted the second annual conference of the Society for Heart Failure and Transplantation (SHFT) at Hotel Hilton Garden Inn, Trivandrum on October 18th and 19th 2014.

Experts from abroad and across India attended the meeting and took part in the discussions. Prof Robert Bonow, North-western University USA who lead many guideline committees of American Heart Association and American College of cardiology was the key International Faculty. Other International faculty were Dr. Jayan Parameshwar, Papworth Hospital, the United Kingdom who is a specialist in cardiac transplant, Dr Mark Huffman from North-western University USA and cardiac electrophysiology specialist, Dr Syamkumar Menon from Mc Master University, Canada.



**Figure 3:** Meeting of the Society of heart failure and Transplantation – View of the Interaction



**Figure 4:** Meeting of the Society of heart failure and Transplantation – Prof. Robert Bonow, USA, delivering the Keynote Address.

Almost all the National experts in the field of Heart failure and cardiac transplant attended the meeting. Around 200 delegates from all over the country attended the meeting.

## **2. Cardiac Biomarker ST2 in Heart Failure patients**

ST2 is a new biomarker which is reflective of fibrosis which is associated with heart failure. We have estimated serial levels of ST2 in 50 patients admitted under the HF program. The ST2 levels are serially assessed and the data regarding the long term outcome of these patients are being collected. 5 patients out of 50 have died at follow-up of 9 months. Now ST2 is commercially available in India.

## **3. Developing patient education materials in Local language (Malayalam).**

Patients with heart failure and their relatives are not very well aware about the disease and its treatment and also the ways to prevent it. There are no study materials available in Indian context and also in the local language Malayalam. We have initiated a project (Project number 5265, Funded by Center for Chronic Disease Control New Delhi, Total funds 4.5 Lakh INR) to develop patient education materials related to heart failure in Indian Context and also in the local language Malayalam. We have already developed some drafts and is being tested among patients with heart failure attending the HF clinic.



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## **WCC 2014 Scientific programme topics**

The following scientific topics will be developed and covered during the WCC 2014 by world-renowned speakers:

- Arrhythmias / Sudden cardiac death / Electrophysiology
- Heart failure / Cardiac function/ Myocardial – pericardial diseases
- Valvular disease / Aortic disease / Pulmonary circulation
- Ischaemia / Coronary artery disease/ Coronary interventions
- Peripheral circulation / Stroke / Non-coronary interventions
- Hypertension
- Epidemiology/ Prevention
- Health promotion / Health advocacy / Global cardiovascular resources
- Basic science
- Cardiac imaging / Information systems
- Pediatrics / Congenital heart disease (pediatric and adult)
- Indigenous health / Rheumatic heart disease
- Nursing / Allied health / CV rehabilitation



## **International and regional topic group leaders**

### **Arrhythmias / Sudden death / Electrophysiology**

Ma Chang Sheng, China  
Mark Estes, United States  
Peter Kistler, Australia

### **Heart failure / Cardiac function / Myocardial – Pericardial diseases**

David Kaye, Australia  
Harikrishnan Sivadasanpillai, India  
Karen Sliwa, South Africa

### **Valvular disease / Aortic disease / Pulmonary circulation**

Paul Bannon, Australia  
Robert Bonow, United States  
Anita Saxena, India

### **Ischaemia / Coronary artery disease / Coronary interventions**

Ge Junbo, China  
Spencer King III, United States  
Ian Meredith, Australia  
Patrick Serruys, Netherlands

### **Peripheral circulation / Stroke / Non- coronary interventions**

Mark Creager, United States  
Albertino Damasceno, Mozambique  
James Shaw, Australia

### **Hypertension**

Louise Burrell, Australia  
Suzanne Oparil, United States  
C. Venketa S. Ram, India/USA

### **Epidemiology / Prevention**

Fernando Lanas Zanetti, Chile  
Anuskha Patel, Australia  
Dong Zhao, China

### **Health promotion / Health advocacy / Global cardiovascular resources**

Eduardo Bianco, Uruguay  
Robert Grenfell, Australia  
Rachel Kitonyo, Togo  
Nizal Sarrafzadegan, Iran





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## World Congress of Cardiology 2014 online programme

### Session details

Member Session World Heart Failure Society session - Meet the experts: Different heart failure management is required for different settings  
*02. Heart Failure*

109+110 Date: Wednesday 7th From: 14:00 To: 15:30

Chair: *Amam Mbakwem, Nigeria*

Chair: *Esaqig Kazzam, United Arab Emirates*

14:00 - 14:18

Heart failure in Latin America

775

Speaker: *Felipe Martinez, Argentina*

14:18 - 14:36

Heart failure in India

557

Speaker: *Harkrishnan Sivadassampal, India*

14:36 - 14:51

Oral abstract - O204 Clinical presentation, management, and in-hospital outcomes of patients admitted with decompensated heart failure in Trivandrum, Kerala, India

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