NATIONAL HEART FAILURE REGISTRY - ICC

Heart failure is the commonest cardiac cause for hospitalization. The average life expectancy has increased over the past decade, but still way behind that in the developed countries. The prevalence of coronary risk factors namely diabetes, hypertension and dyslipidemia are on the rise. Though there has been improvement in the treatment of coronary artery disease, the incidence of heart failure is increasing. To address this issue and to make progress there is indeed a need for a true and meaningful data of the prevalence, etiology, diagnosis, treatment patterns and follow up of these patients across the country.

Background and rationale

Heart failure prevalence accounts for 1-3% of the population, 5-10% in persons between 65-79 years and 10-20% in elderly above 80 years of age. Heart failure is the commonest cause for rehospitalisation in elderly after hospital discharge. Heart failure has become a global epidemic and most of the data is available from higher income countries. Various registries like Global Congestive Heart Failure Registry (G-CHF) and Inter CHF Registry are addressing these issues[1]. Congestive Heart Failure Registry also showed high mortality in India.

INTRODUCTION

As per projections there are at least 8–10 million patients with HF in India with a prevalence of about 1% adult population. Studies done from Trivandrum and Hospital-based studies from All India Institute of Medical Sciences (AIIMS) suggest that rheumatic heart disease (RHD) and coronary artery disease (CAD) are both major causes of heart failure in India.

STATUS OF HEART FAILURE IN INDIA

The Trivandrum HF registry (THFR)[2] enrolled 1205 admissions for HF (834 men, 69%). The mean age was 61.2 years. The most common etiology of HF was ischemic heart disease (72%). HF with preserved ejection fraction (HF$_p$EF) constituted 26%. Patients with HF in the Trivandrum HF registry were younger, and had a higher prevalence of CAD.

In another study from AIIMS, adults of six villages in Northern India were screened, and cases of dyspnea were identified by trained health workers. Of 10,163 cases screened,

the prevalence of HF in this rural community was estimated to be 1.2/1000. Two-thirds of the patients had HFpEF and all of them had uncontrolled hypertension (HTN).[3]

In another study of 1985 patients from North India the mean age was 49.2 years[4]. The mean age in THFR was 61.2 years, meaning that this population from North India is much younger, compared to South Indian patients and still younger than patients of Western India. In the in-hospital group, RHD (52%) was the most common cause followed by ischemic heart disease (17%). RHD (37.1%) was the most common etiology followed by CAD (33.4%) in a tertiary hospital cohort[4]. One reason for the higher rates of RHD could be due to the referral bias of patients from the low socioeconomic sector to public sector hospitals where the study was conducted.

Since Indian patients with HF are different and respond differently to therapy, it is necessary to create guidelines in HF therapy which are specific to Indian patients. An exercise was carried out wherein experts from AIIMS, RML, SJH, GB Pant, PGI Chandigarh and Care Hospitals got together to create a consensus statement on the management on HF in India along with members of European Society of Cardiology (ESC).[5]

Recently published data shows a high prevalence of diabetes and hypertension in India (7.5% & 25.3%) respectively[6]. Dyslipidemia is on the rise (79%) as evident from the ICMR- INDIAB study[7]. CHD prevalence in India has increased and estimated to be around 30 million. Hence heart failure would be a major reason for morbidity and mortality. Thus this increased burden at a young age leads to loss of productivity and is a barrier for economic growth. There is paucity of good and reliable data in India on heart failure in the country and once a true and meaningful national data is available, the identification of risk factors, available treatment options and challenges in management could be addressed.

Many heart failure registries in the developed world have contributed to better understanding of heart failure and thus helpful in formulating plans to address relevant issues. In India some small scale studies have been done. However the treatment patterns and issues are different across various geographical areas in India. A state like Kerala with high literacy rates with better access to health care both in private and government hospitals is vastly different from a state like West Bengal. This study would have representative groups from all over the country and the plan is to start enrollment in the Southern part of the country involving Kerala, Tamilnadu, Karnataka, Andhra Pradesh & Telangana. The plan is to spread the registry to the remaining parts of the country in a phased manner.

Patients with HF in India are younger, sicker and have a much higher morbidity and mortality as compared to their western counterparts. They also do not tolerate the high level of medications recommended in western guidelines. Similarly, devices and other advanced therapies are often too costly and out of reach of many of our sick patients.

Objective

This is to document the demographics, clinical patterns, diagnostic and therapeutic strategies in patients presenting with heart failure across various states in India. This would include patients with acute heart failure during their hospital phase.

Baseline data will be obtained on clinical presentation, demographics, laboratory parameters, ECG, CXR, Echocardiography. The diagnostic patterns, treatment protocol and practice patterns will be documented. These patients will be followed up at 30 days, and 1 year. This is a prospective observational registry designed to enroll patients with heart failure in a pan Indian Population. The study would commence with a enrollment first in South India involving 10-12 centres and would extend to the rest of India after six months to 1 year.

This data would give an insight into the various etiological factors, co-morbid conditions, diagnostic modalities used and practice patterns and challenges faced in heart failure treatment. The economic impact, gap in guideline directed treatment and follow up could be addressed. This would help in planning better utilisation of resources which may have to be modified in a country like India.

Study plan

The aim is to enroll 10,000 patients across India both in private and government set up. Enrollment would take place all over India in a phased manner. The centers chosen would be in 4 zones (South, North, East and North East, West and Central). Each zone would have 10-12 centers. Each zone would have a Zonal co-ordinator who could co-ordinate the training, participation and enrollment of patients in the registry in his zone with the help of state co-ordinators. The state co-ordinator in turn would supervise and facilitate data entry and follow up of every site in his state. Each site would have a site co-ordinator who would be responsible for the data entry and follow up of patients in his center. For a successful registry quality of data entry is very important. For this purpose site co-ordinator could delegate this work to physician or ICU nurse.

This proforma has been earlier run in hospitals in Kerala and found to be very simple to gather and document. The validation, structure and processes have been tried out in the various registries in Kerala. It is important that the data acquired be communicated to the nodal centre. Each site and the state co-ordinator would be periodically contacted from the registry head quarters so as to constantly update the progress of the registry.

It is mandatory to have an Ethics Committee (EC) approval for the registry. If the institute has an Ethics Committee, it is recommended to get clearance from the local EC. If there is no local EC, approval for the concerned center could be obtained from the central SJIC EC. Primary data collection will be for one year form 1st August 2018, and the patients followed up telephonically / clinically at 30 days, and 1 year. During clinical follow up, Echo and BNP would be an additional information but not mandatory.

Primary outcome

This is to obtain the clinical, demographic, and etiological factors of HF in the country. Estimates of mortality, nonfatal outcomes, and rehospitalization would also be obtained.

Secondary outcome

To understand the diagnostic and therapeutic options offered and also to understand the prognostic parameters and practice patterns.

Inclusion criteria

Patients above 18 years of age with a clinical diagnosis of Acute HF seen in hospital ICU/ward of the participating centres.

Exclusion criteria

Patients not willing and available for follow up

Study design

Study type.   :   Observational (patient registry)

Enrolment   :   10,000 participants

Model   :   Cohort

Time perspective   :   Prospective

Duration   :   1 year

Title   :   Heart failure Registry - ICC

START DATE   :   August 2018

Estimated completion date: August 2020

REFERENCES

1. HishamDokainish, Koon Teo, Jun Zhu, et al. on behalf of the INTER-CHF Investigators. Global mortality variations in patients with heart failure: Results from the International Congestive Heart Failure (INTER-CHF) prospective cohort study. *Lancet Global Health* 2017;DOI:10.1016/S2214-109X(17)30196-1

2. Harikrishnan S, Sanjay G, Anees T, Viswanathan S, Vijayaraghavan G, Bahuleyan CG, et al. Clinical presentation, management, in-hospital and 90-day outcomes of heart failure patients in Trivandrum, Kerala, India: The Trivandrum Heart Failure Registry. Eur J Heart Fail. 2015;17:794-800.

3. Huffman MD, Prabhakaran D. Heart failure: Epidemiology and prevention in India. Natl Med J India. 2010;23:283-8.

4. Chaturvedi V, Parakh N, Seth S, Bhargava B, Ramakrishnan S, Roy A, et al. Heart failure in India: The INDUS (INDiaUkieri Study) study. JPCS. 2016;2:28-35.

5. Seth S, Bhargava B, Maulik SK, McDonagh T, Saxena A, Airan B, Calambur N, HoteMParakh N, Bahl A, Ramakrishnan S, Chaturvedi V, Nath R, ChakroborthyP.Consensus statement on management of chronic heart failure in India. 2015;2(1):105-12.

6. Pascal Geldsetzer, MBChB; Jennifer Manne-Goehler, MD; Michaela Theilmann, BA; et al. Diabetes and Hypertension in IndiaA Nationally Representative Study of 1.3 Million Adults. JAMA Intern Med. 2018;178(3):363-372.

7. Joshi SR, Anjana RM, Deepa M, Pradeepa R, Bhansali A, Dhandania VK at el. ICMR-INDIAB Collaborative Study Group. Prevalence of dyslipidemia in rural and urban area:ICMR-INDIAB Study.PLoS One 2014 9,9:e96808