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Profiling cardiac arrhythmia and heart failure patients in India: The Pan-arrhythmia and Heart Failure Observational Study

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ABSTRACT

Background: The PANARrhythMia and Heart Failure Registry (PANARM HF) characterized demographic, clinical and interventional therapy indication profiles of cardiac arrhythmia (CA) and heart failure (HF) patients in India.

Methods: Consulting Physicians (CP) who medically manage CA and HF patients enrolled patients with one or more of the following: syncope, pre-syncope, dyspnea, palpitation, fatigue and LV dysfunction. The CPs were trained by interventional cardiologists (IC) to identify CA/HF patients indicated for implantable device/radiofrequency ablation (RFA). 59 CP's, 16 IC's & 2205 patients from 12 cities participated. Demographic, clinical, device/RFA indication and referral-consultation profiles were created. IC's provided device/RFA recommendations based on these profiles.

Results: The CA/HF distribution of patients was: HF – 58%, bradyarrhythmia – 15%, atrial fibrillation – 15%, other supraventricular tachyarrhythmia – 10% and ventricular tachycardia/fibrillation – 4.5%. 62% of the CA/HF population was male and 45% were below age 60. Coronary artery disease (52%), hypertension (44%), diabetes (30%) & myocardial infarction (20%) were prominent. 1011 (46%) of the CA/HF population were potential device/RFA candidates according to the IC's. However, only 700 (69%) of these patients were referred to the IC by the CP. Of referred patients, only 177 (25%) consulted the IC and were recommended therapy. Thus, 824 (83%) of patients indicated for interventional therapy were not advised therapy or did not opt for it.

Conclusion: The India PANARM HF study provides new information and insights into the demographic, clinical, interventional therapy, referral and consultation pattern profiles of CA/HF patients in India.

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1. Introduction

Cardiovascular diseases like heart failure (HF) and cardiac arrhythmias (CA) form a major component of the non-communicable disease burden in the Indian population.[1–7] Approximately 40,000–50,000 CA/HF patients receive interventional device therapies like pacemakers, implantable cardioverter defibrillators (ICD), cardiac resynchronization therapy (CRT) and/or radio-frequency ablation (RFA) annually in India.[8–10] However, there is very limited published information that systematically profiles Indian HF and CA patients. There is virtually no insight into the diagnostic and interventional treatment access process for these patients.

We implemented a clinical registry that enrolled 2205 CA/HF patients presenting to 59 non-interventional consulting physicians (CP) across 12 cities in India and used a diagnosis protocol (DP) to characterize their demographic, cardiovascular, interventional device/RFA therapy indication profiles and referral/consultation patterns. The results from such a registry could provide a basis for healthcare practitioners, policy makers, payers and medical administrations for improving the overall management and access to treatment for patients suffering from CA and HF. Also, the information gained from the registry could be used to increase physician awareness, diagnosis & therapy prescription and outline improved processes for HF and CA management.

2. Methods

The PANARM HF registry, a prospective, multi-center, non-interventional, observational study was conducted during November, 2008 to March 2010 in compliance with currently accepted ethical considerations and according to the principles outlined in the 'World Medical Association Declaration of Helsinki' (October 2000). All patients provided written consent for the release of their anonymized data by signing the study Patient Data Release Form. The study was registered in the Clinical Trial Registry of India (CTRI) database with number as CTRI/2008/091/000204.

Two categories of physicians from across 12 cities in India participated in the registry: 1) 59 non-interventional CP who were MD's or non-interventional cardiologists by qualification, and 2) 16 interventional cardiologists (IC) who were expert practitioners of implantable device therapy, and in several cases, who also perform RFA.

A detailed diagnosis protocol (DP) comprising history and symptom assessment, physical exam, ECG, echocardiographic testing (where applicable) and consensus-guidelines based interventional therapy indication assessment was defined by a group of IC's to classify patients suffering from CA and/or HF and interventional therapy options for these patients. Cardiac arrhythmia and heart failure patients analyzed in the registry were classified as defined in Table 1. The ACC/AHA/HRS ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities[8] were used to identify patients indicated for pacemaker, ICD and CRT. The ACC/AHA Guidelines for Clinical Intracardiac Electrophysiological and Catheter Ablation Procedures[9] were used to identify patients indicated for RFA. All participating CP's were trained on implementing the DP by IC's during study training meetings that preceded CP enrollment into the study. In addition, a variety of educational tools were provided to the CP to supplement the DP and aid in the diagnosis & therapy assessment process . Bimonthly study review meetings between ICs and their assigned CPs were encouraged. Fig. 1 shows a flow chart of the study process.

CP's evaluated all patients presenting to them and identified patients eligible for enrolment according to the following inclusion criteria: 1) patients with one or more of the following symptoms secondary to CA and/or HF – syncope, pre-syncope, dyspnea, palpitations, fatigue, and/or 2) left ventricular dysfunction (left ventricular ejection fraction (LVEF) $\leq$40% measured through echocardiogram), 3) patients who had signed and dated a Patient Data Release Form specified in this study plan, and 4) patients who were at least 18 years of age at the time of enrolment. The following patients were excluded: 1) patients with HF arising out of primary valvular diseases 2) patients with acute myocardial infarction

Table 1
Heart failure and cardiac arrhythmias diagnosis definitions.

Patient Cohort	Definition	Assessor
Heart Failure	• HF stage B/C/D, LVEF $\leq$40% NYHA Class II/III/IV • LVEF >40%, HF Stage C/D, NYHA Class III/IV	IC
SCA Primary Prevention – Ischemic	• LVEF$\leq$ 30% based on echocardiographic testing • Old MI (>6 weeks) based on history/ecg/echo • NYHA I or II or III based on history/symptoms	CP
SCA Primary Prevention – Non-ischemic	• NYHA II or III based on history/symptoms • LVEF $\leq$30% based on echocardiographic testing • No Coronary artery disease based on history • No MI based on history	CP
Bradyarrhythmia	• Sinus Node Dysfunction – ECG based • 3° Atrial Ventricular (AV) block – ECG based • 2° AV block Type 2 – ECG based • 2° AV block Type 1 – ECG based • 1° AV block – ECG based • Chronic Atrial Flutter with ventricular bradycardia – ECG based • Carotid Sinus Syndrome – ECG & screening	IC
Atrial Fibrillation	• Atrial fibrillation – ECG based	IC
SVT	• Atrial flutter – ECG based • Atrial tachycardia – ECG based • Paroxysmal SVT – ECG based	IC
(MI)	• Old MI (>6 weeks) based on history/ECG	CP

HF = Heart Failure; LVEF = Left Ventricular Ejection Fraction; SCA = Sudden Cardiac Arrest; MI = Myocardial Infraction; SVT = Supraventricular Tachyarrhythmia.

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