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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-syncpe, 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 radiofrequency 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] <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 ≤40% NYHA Class II/III/IV | IC |
| | • LVEF >40%, HF Stage C/D, NYHA Class III/IV | |
| SCA Primary Prevention – Ischemic | • LVEF ≤ 30% based on echocardiographic testing | CP |
| | • Old MI (>6 weeks) based on history/ECG/echo | |
| | • NYHA I or II or III based on history/symptoms | |
| SCA Primary Prevention – Non-ischemic | • NYHA II or III based on history/symptoms | CP |
| | • LVEF ≤30% based on echocardiographic testing | |
| | • No Coronary artery disease based on history | |
| | • No MI based on history | |
| Bradyarrhythmia | • Sinus Node Dysfunction – ECG based | IC |
| | • 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 | |
| Atrial Fibrillation | • Atrial fibrillation – ECG based | IC |
| SVT | • Atrial flutter – ECG based | IC |
| | • Atrial tachycardia – ECG based | |
| | • Paroxysmal SVT – ECG based | |
| (MI) | • Old MI (>6 weeks) based on history/ECG | CP |

HF = Heart Failure; LVEF = Left Ventricular Ejection Fraction; SCA = Sudden Cardiac Arrest; MI = Myocardial Infarction; SVT = Supraventricular Tachyarrhythmia.
(<40 days), 3) patients with electrolyte imbalance, acute pulmonary embolism, pneumothorax and other acute syndromes/events that are reversible, and 4) patients with recent percutaneous coronary intervention or cardiovascular surgery (<40 days in the past).

A CP case report form (CP CRF) that captured the patient’s demographic, symptom, cardiovascular, disease etiology and therapy indication profile, including ECG for all patients and echocardiographic report for patients with LV dysfunction were completed for all enrolled patients by the CP. All patients who required further evaluation by IC for implantable device therapy/RF ablation in the CP's judgment were counselled and referred to the CP's designated IC participating in the registry for further evaluation and treatment. Patients who did not require interventional therapy in the CP's judgment were not referred to the IC and were prescribed drug management by the CP.

CP CRF, ECG and echo reports for all patients, both referred and not referred by the CP, were transferred to designated IC from the CP on a monthly basis. IC's recorded the final diagnosis, disease etiology and therapy prescription in an IC CRF for each patient. All information recorded in the CP CRF and IC CRF was analyzed to construct detailed demographic, clinical and device/RFA therapy indication profiles for CA/HF patients presenting to the CP. Continuous data are reported as mean and standard deviation. Categorical data are reported as frequencies (N) and percentages (%). This was a non-comparative study and therefore no statistical testing was performed.

### 3. Results

2205 patients who met study inclusion/exclusion criteria were enrolled in the study. An average of 37 patients was enrolled per CP by the 59 CP contributing to the study population.

#### 3.1. Demographic and clinical profile

Table 2 shows the clinical and demographic profiles of the total registry population and Table 3 that of the HF sub-population. Fatigue, dyspnea and palpitations were the most common symptoms, 76% patients having multiple symptoms and 30% of

| LV dysfunction patient (EF<40%) or symptomatic patient consults CP |
|---------------------------------------------------------------|
| syncope | pre-syncope | palpitations | fatigue | dyspnea |

CP evaluates the patient as per the diagnostic data collection protocol & the RP CRF

| Heart Failure w/o need for CRT |
|--------------------------------|
| VT/high risk for cardiac arrest w/o need for ICD, RF ablation |

CP makes a diagnosis of one or more of the following:

Physician explains study details & patient signs data release form to enroll in study CP completes RP CRF in triplicate (Original - Medtronic, RP copy, Patient Copy) & obtains 2 copies of ECG test and Echo test results - CRO collects RP CRF & test results on a monthly basis for transfer to cardiologist and entry into database

For all referred patients CP additionally

| Performs patient counselling |
|-----------------------------|
| Completes Referred Patient section of RP CRF |

Referred patient consults IC with Referral Form, RP CRF & test results - Additional tests conducted by implanting cardiologist as required. Referred patient does not consult implanting cardiologist OR Patient not referred to implanting cardiologist – Medtronic/CRO collects RP CRF & test results from physician every month and provides to implanting cardiologist for evaluation

| Completes Patient Referral Form |
|--------------------------------|
| Provides patient with RPCR, Patient Referral Form (optional), ECG & echo results |

IC completes IC - CRF for referred consulting, referred not consulting & not referred patients – in triplicate (Original - Medtronic, IC Copy, RP Copy)

If interventional therapy is required for the patient, RP copy of the IC CRF sent to the CP either through the consulting patient, through Medtronic or directly by the physician

For not referred patients or referred not consulting patients who are recommended interventional therapy by the cardiologist, the CP informs the patient & counsels as required

CRO collects all IC CRFs on a monthly basis and captures patient demographic & cardiovascular profile/etiology of HF from CP & IC CRF

Fig. 1. Schematic of PANARM HF Registry Process.
patients had experienced syncpe/pre-syncope. 51 (2%) patients did not have symptoms at the time of enrollment and were included in the study because they had LV dysfunction.

With 1272 (58%) registry patients suffering from HF, it was the most prevalent syndrome followed by bradycardia 15%, atrial fibrillation – 15%, other supraventricular tachyarrhythmia – 10% and ventricular tachycardia/fibrillation – 4.5%. Approximately 401 (31%) patients of the HF population were also at high risk for Sudden Cardiac Arrest (SCA). The majority of the HF population was in an advanced state of HF, with about 1042 (82%) patients being in Stage C and D, 814 (64%) with LVEF ≤ 30% and 486 (38%) patients with a QRS width ≥ 120 ms.

The bradyarrhythmia population totalled 266 (12%) patients (mean age 63.5 ± 13.5), with 146 (55%) Sinus Node Dysfunction (SND) patients and 120 (45%) 2nd and 3rd degree AV block patients. The SND patients were significantly symptomatic with 79% presenting with syncope/pre-syncope, 62% with fatigue and 48% with dyspnea greater than New York Heart Association (NYHA) Class II. 19% of SND patients had LV dysfunction with EF ≤ 40%. Higher incidence of SND was observed from the 6th decade onwards and AV block a decade earlier. In addition to syncope, fatigue was a significant symptom in both SND and AV block.

20% of the registry population had a prior MI and about 52% were known to have CAD. Hypertension was prevalent in 44% and diabetes in 30% of the patients. At least 50% of the patients in this study had ventricular dysfunction with an ejection fraction LVEF ≤ 35%. Approximately 37% of the patients had advanced heart failure (NYHA III/IV) at the time of enrollment and 30% were NYHA Class II.

3.2. Therapy recommendation and patient referral patterns

As shown in Fig. 2, 1011 out of 2205 (~46%) patients were identified to potentially benefit from pacemaker, ICD, CRT or RFA by the IC. Nearly 50% of the registry patients were identified for medical management only and about 5% needed further evaluation. 11 patients were identified for procedures like revascularization, valve repair/replacement etc. that were outside the scope of this study. In particular, 289/1272 (23%) of the HF patients and 722/1379 (52.4%) of CA patients were classified by ICs as potentially needing interventional device or RFA therapy.

Analysis of the CP referral patterns for the 1011 patients identified by the IC as potentially benefitting from interventional showed that only 700 (69%) of these patients were referred to the IC by their CP and 311 (31%) were not. Analysis of the IC consultation patterns for the 700 referred patients showed that only 177 (~25% of referred patients) consulted the IC – the remaining 523 patients identified by the CP and another 311 not identified by the CP, who could have potentially benefited from interventional therapy did not consult the IC to whom they were referred within the duration of the study. Thus, only the 177 patients who consulted the IC were actually prescribed therapy, while for the remaining 834 patients who could have benefited from interventional therapy, the opportunity to receive this therapy was unavailable. This referral, consultation and prescription pattern is depicted in Fig. 3.

4. Discussion

To our knowledge, the PANARM HF registry represents the first study that characterizes the demographic, cardiovascular, interventional device or RFA therapy indication profiles and referral specialist consultation patterns of over 2000 patients with HF and/or CA symptoms presenting to non-interventional consulting physicians across India.
4.1. Demographic and clinical profile of arrhythmia and heart failure patients

The majority of the patients (62%) were male. A similar gender ratio was shown in the 11th World pacing survey in patients receiving pacemaker implants in India. The imbalance between male and female recipients of implantable devices or interventional therapies is much lower in the developed world. In India this imbalance could be due to a combination of factors such as reduced cardiovascular disease prevalence amongst females, reluctance to seek healthcare and, more likely, a lower priority and willingness to finance female health in Indian society.

Close to half the population was <60 years, which is lower compared to similar cohorts in other parts of the world. Data from the Framingham Heart Study indicate that the mean age at the diagnosis of HF was 70 years. In the western population the average age of patients receiving pacemakers for SND is about 75 years. This is an important finding of our study which indicates an early disease onset, which aligns well with premature onset of cardiovascular risk factors and lower average life-span of 67 years for males and 69 years for females in India.

Prevalence of heart failure (58%) and cardiac arrhythmias (22% at high risk for SCA, 15% suffering from atrial fibrillation, 15% from bradycardia) in our study of course derive from the study design and selection criteria. It is noteworthy that a significant percentage (>50%) of patients with HF or CA symptoms were actually found in a fairly advanced stage of cardiovascular disease, as shown by the fact that 82% of HF patients were in stage C or D HF and 722/1379 (52.4%) CA patients were candidates for interventional therapies. This finding is a clear reflection on the lack of health awareness amongst the Indian population, low priority to pro-actively seek out healthcare and limited availability and access to tertiary care centers.

Given the high proportion of patients with LV dysfunction in the registry, a significant cohort of 401 registry patients (18%) had a clinical profile that placed them in the primary prevention risk category for SCA. 46% of these patients had non-ischemic cardiomyopathy which is higher in comparison to registries that studied patients indicated for ICD therapy for SCA primary prevention from other parts of the world. The non-ischemic group was younger (34.5% ≤51 years), had a higher ratio of females, lower hypertension and diabetes but a higher percentage of patients with a broad QRS. These patients could represent a high focus group for therapy access due to the potentially higher benefit they may gain from cardiac resynchronization therapy as compared to the more co-morbid and advanced-stage ischemic cardiomyopathy patients.

Of the 2205 patients enrolled in the study, 331 (15%) patients suffered from bradyarrhythmias, with a higher percentage of SND patients (44%) compared to heart block patients (36%). The 11th World pacing survey showed only 23% of patients receiving pacemakers in India for SND versus 58% for advance heart blocks. Thus, it appears that despite being symptomatic, a significant proportion of SND patients do not receive pacemakers in India, likely due to the relatively benign nature of the disease and limited severity of their symptoms. The age distribution of the SND population indicated that 70% of the patients were below the age of 70, whereas in the western population the average age of patients receiving pacemakers for SND was 75.
Atrial fibrillation or other supraventricular tachyarrhythmias were documented in 551 (25%) patients. The actual prevalence of atrial tachyarrhythmias in the evaluated patients is probably higher due to undocumented intermittent and asymptomatic forms of tachyarrhythmias. 70% of the AF patients were below the age of 70, indicating an earlier onset of disease compared to the west.13 The percentage of women was relatively higher in this cohort, at 48% versus an overall female study representation of 38%.

4.2. Interventional therapy indication

Out of 2205 patients, selected only on the basis of HF and/or CA symptoms, 1011 (45.8%) could benefit from interventional device therapy/ablation. As shown in Fig. 2, the percentage of patients indicated for interventional therapy varied according to their disease condition, ranging from 23% for HF patients, 34% of AF/SVT patients, 55% for bradycardia patients and 73% for patients with primary and secondary SCA risk. Cardiac implantable pacemakers and ICD are well established interventional therapies to treat CA patients.3 Similarly, CRT devices are indicated in patients with LV systolic dysfunction, moderate to severe heart failure symptoms and wide QRS > 120 ms, despite optimal medical therapy.4 Finally, RFA has recently been proposed as effective treatment of drug refractory AF.5 The cost of these devices and therapies is a limiting factor in the Indian healthcare system and these therapies are beyond the reach of many patients. However, those who can afford them should be referred to centres and cardiologists experienced in performing these interventional therapies.

4.3. Referral patterns and therapy adoption

Large volumes of advanced cardiovascular diseases are managed by CP in India. Before the study started, CP were characterized by large differences in the knowledge and application of diagnosis, ECG analysis and interventional therapy guidelines for CA/HF patients. The study training programs, diagnostic protocol and tools were deemed of significant value by the CP in enhancing their knowledge and systematizing their approach to patient screening, diagnosis, counselling and referral.

Despite this training, 311/1011 (31%) patients who could benefit from interventional therapy were not referred to IC, as shown in Fig. 3. Similarly 50% of patients who did not need interventional therapy were unnecessarily referred to the IC. Of 1011 patients who could have benefited from interventional therapy, only 177 consulted IC’s (17%) due to both inadequate referral (only 69% of patients requiring interventional were referred by CP to IC) as well as poor IC consultation compliance by referred patient(Fig. 3). Since correct identification of indicated patients and patient counselling were issues at the CP level, our data suggest the need for continuous education strategies and simple diagnostic algorithms for improved screening and diagnosis at physician level and for enhanced patient counselling.

In particular our study indicates that CP in India manage significant volumes of primary prevention for SCA patients, many of them with relatively early disease onset and non-ischemic etiology. Unfortunately only a minority of ICD indicated patients were referred and actually received an ICD. ICD therapy for patients meeting primary prevention consensus guidelines is significantly under-utilized all over the world.15–17

The key study results are 1) a significant portion of the study population, selected for having HF and CA symptoms, was found in a fairly advanced stage of cardiovascular disease at the time they consulted the physician, 2) almost half the patients with HF and/or CA symptoms would warrant an interventional device therapy or ablation but 3) even in the study controlled environment only 17% of indicated patients consulted an interventional specialist and were prescribed with an interventional therapy.

The study provides substantial new information about health care gaps in India and meaningful insights that can be applied to enhance diagnosis, therapy access and management of these patients. Our results may be valuable for healthcare providers, policy makers, payers and medical administrations to define and implement strategies focused on reducing the disease burden of HF and CA. Our data suggest to focus on enhancing identification, counselling and referral of CA/HF patients indicated for interventional therapy by consulting physicians to specialists who can provide these therapies. In addition, initiatives toward patients education are warranted. The fact that the majority of patients consult physicians only after disease has progressed to advanced stage, as shown in our data, suggest the need for improving patient awareness about cardiovascular diseases and enhancing patients’ attitude toward proactive healthcare-seeking behaviour through frequent consultation with specialists and acceptance of therapy upon prescription. Finally, it is important for the government, care providers, reimbursement groups, medical insurance and industry to establish innovative programs to address affordability and liquidity barriers that prevent patients prescribed interventional therapies from adopting them.

4.4. Limitations

This was a prospective observational research. The limitations of multicentre observational studies, such as potential bias in patient selection and patient referral and the lack of a control group, apply to our research. The fact that the study was preceded by training on diagnosis and therapy guidelines and that research endpoints were pre-specified possibly mitigated patient selection and referral biases. In addition, the results of the study are limited to the evaluated population of subjects with HF and/or CA symptoms.

5. Conclusions

Through an observational study we found that a significant portion of patients with HF or CA symptoms, presenting to non-interventional consulting physicians across 12 cities in India, was in a fairly advanced stage of cardiovascular disease. In fact almost half the patients were indicated for interventional device therapy or ablation. We found that, even in the study controlled environment, only a minority (17%) are prescribed the indicated interventional therapy. In particular, while therapy penetration was fair for pacemaker and RF ablation therapy, it was minimal for CRT and ICD. Healthcare quality improvement strategies are warranted to reduce the HF and CA disease burden.

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Appendix A. List of participating Investigators, Institutions

| Serial No. | Investigator Name | Role in the study | Study Center | City | State | Zone |
|------------|-------------------|-------------------|--------------|------|-------|------|
| 1          | Dr. Ajay Naik     | Implanting Cardiologist | Heart Care Clinic, 201,2nd Floor Balleshwar Avenue, Opposite Rajpath Club S G Highway, Ahmedabad-380054 | Ahmedabad | Gujarat | West |
| 2          | Dr. Sunil Mehta   | Consulting Physician | 9th floor Doctor House, Near Farimal Crossing, Ahmedabad-380006 | Ahmedabad | Gujarat | West |
| 3          | Dr. Dhiren Joshi  | Consulting Physician | Shashi Shopping Centre, Near Anjali Cinema, Jawanagar, Ahmedabad-380007 | Ahmedabad | Gujarat | West |
| 4          | Dr. Gaurav Chhaya| Consulting Physician | Shivam Medi Care Clinic, UK-2, Vrajbhoomi Complex, Opposite Riddhi Tower, Jodhpur Gam, Near Rosewood Tower, Ahmedabad – 380015. | Ahmedabad | Gujarat | West |
| 5          | Dr. Jayesh Shah   | Consulting Physician | Sharada Medical Nursing, Plot No. 904/1, Opposite Gh - Road, Sector – 7 – C, Gandhinagar -382007 | Ahmedabad | Gujarat | West |
| 6          | Dr. Kirti Akhani  | Consulting Physician | Troupi Heart & Medical Hospital, 3rd Floor, Saiked Complex, Opposite Petrol Pump, Mangle Park, Geetamandir Road, Ahmedabad – 380022. | Ahmedabad | Gujarat | West |
| 7          | Dr. Raghu Satyanarayanan | Consulting Physician | 5th Floor , Ankur Complex, Anukr, Naranpura, Ahmedabad | Ahmedabad | Gujarat | West |
| 8          | Dr. Aparna Jainal | Consulting Physician | Escorts Heart Institute and Research Centre, Okhla road, New Delhi-110025 | New Delhi | New Delhi | North |
| 9          | Dr. A.K. Manchanda | Consulting Physician | D-47, Bali Nagar, New Delhi-100015 | New Delhi | New Delhi | North |
| 10         | Dr. A.K. Ashish   | Consulting Physician | A block, Janakpuri, New Delhi-110 058 | New Delhi | New Delhi | North |
| 11         | Dr. I.J. KALRA    | Consulting Physician | DA-3A,LIG Flats, Behind DA-block, Hari Nagar, New Delhi 110018 | New Delhi | New Delhi | North |
| 12         | Dr. Rajesh Gupta  | Consulting Physician | 7, Local Shopping Centre, Derawal Nagar, Gujranwala Town Phase IV, Delhi-110009 | New Delhi | New Delhi | North |
| 13         | Dr. Gagan Kaushal | Consulting Physician | Life Care Hospital, Near Community Center Main Market Sector-7, Urban Estate, Karnal, Haryana -132001 | Karnal | Haryana | North |
| 14         | Dr. Jitendra Singh Makkar | Consulting Physician | Fortis Escorts Hospital, Malviya Nagar, Jaipur - 302017 | Jaipur | Rajasthan | North |
| 15         | Dr. Sanjeev Gupta | Consulting Physician | 7 KHA-11,Jawahar Nagar, Jaipur | Jaipur | Rajasthan | North |
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| 17         | Dr. Puneet Rijhwani | Consulting Physician | 14/201,Malviya Nagar, Jaipur-17 | Jaipur | Rajasthan | North |
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| 19         | Dr. Anjali Dattal | Consulting Physician | Datal Multispeciality Hospital Thakurdwara Chowk, Distt. Kanga H.P.- 176102 | Kangra | Himachal Pradesh | North |
| 20         | Dr. Manoj Agarwal | Consulting Physician | Aggarwal Heart & Surgical Hospital, Ambala City | Ambala | Punjab | North |
| 21         | Dr. Chandu Bowery | Consulting Physician | 72-73 Udhan Singh Nagar Jalandhar | Jalandhar | Punjab | North |
| 22         | Dr. Pramod Sinha | Consulting Physician | Harih Hospital,Gutkar, Mandi,(HP) | Mandi | Himachal Pradesh | North |
| 23         | Dr. Gursharan Singh Sidhu | Consulting Physician | Sidhu Hospital, Doraha, Punjab | Ludhiana | Punjab | North |
| 24         | Dr. V.P. Mahajan | Consulting Physician | Mahajan Clinic, Shyam Nagar Dharamsala, H.P.-176215 | Dharamsala | Himachal Pradesh | North |
| 25         | Dr. Arun Chopra | Consulting Physician | Escorts Hospital, Amritsar | Amritsar | Punjab | North |
| 26         | Dr. Ashok Mahajan | Consulting Physician | Mahajan Nursing Home, Katra Khajana, Amritsar | Amritsar | Punjab | North |
| 27         | Dr. Satinder Aroha | Consulting Physician | Harjeet Nursing Home, Court Road, Amritsar | Amritsar | Punjab | North |
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| 31         | Dr. Tushar Roy   | Consulting Physician | E327, Greater Kailash Part-1, New Delhi-110048 | New Delhi | New Delhi | North |
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| 33         | Dr. Rajesh Madan | Consulting Physician | Ayushman Hospital Sec 12 , Dwarka, New Delhi-110075 | New Delhi | New Delhi | North |
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Appendix B. Consulting Physician Case Report Forms (CP CRF).

**PANARhythmia and Heart Failure Registry**

**Physician Case Report Form**

| Administration & Patient Demographics | Patient ID |
|---------------------------------------|------------|
| Name of physician                     |            |
| Patient status                        |            |
| Outpatient                            | Inpatient  |
| Date patient data release signed      |            |
| ( dd-mm- yyyy )                       |            |
| Age, years                            | Gender     |
| Male                                  | Female     |

**Patient Symptoms** (please tick all that apply)

- Syncope
- Pre-syncope
- Palpitations with sweating
- Angina
- No symptoms
- Other

**Patient Symptoms** (please tick all that apply)

- Dyspnea grade > NYHA Class II
- Past dyspnea if worse
- NYHA Class III
- NYHA Class IV

**Fatigue - moderate to severe**

- Other/Comments, please specify (optional):

**Cardiovascular & Co-morbidity Profile**

(please tick all that apply)

- Left ventricular ejection fraction via Echo (for patients with Stage B, C or D heart failure)
- %
- Coronary artery disease
- Diabetes
- Hypertension
- Myocardial infarction
- Recent (≤ 6 weeks)
- Old (> 6 weeks)
- Prior stroke
- Recent (≤ 6 weeks)
- Old (> 6 weeks)
- Dyslipidemia (Cholesterol > 200 mg/dl, Triglycerides > 150 mg/dl, LDL > 130 mg/dl)
- Unknown

**Other/Comments, please specify (optional):**

**Bradyarrhythmia Evaluation** (please tick all that apply and attach ECG)

- Sinus bradycardia, including sinus pauses with symptoms
- Bradycardia with junctional escape rhythm with symptoms
- 3° AV Block with symptoms and/or escape rate less than 40 bpm
- 2° AV Block – Type 2 with symptoms and/or escape rate less than 40 bpm
- 2° AV Block – Type 1 with symptoms
- 1° AV Block with symptoms
- Chronic atrial fibrillation with symptomatic bradycardia
- Suspected hypersensitive carotid sinus syndrome

**Other, please specify:**

- Patient referred to cardiologist for further evaluation & treatment
- Yes
- No
- If patient is potentially suffering from symptomatic bradycardia but is not referred, please explain why:

**Comments & drug therapy prescribed (optional):**

**Supraventricular Tachyarrhythmia Evaluation** (please tick all that apply & attach ECG)

- Atrial fibrillation
- Atrial flutter
- Atrial tachycardia
- Paroxysmal supraventricular tachycardia (PSVT)

**Other, please specify:**

- Patient referred to cardiologist for further evaluation & treatment
- Yes
- No
- If patient is potentially suffering from supraventricular tachycardia amenable to radiofrequency ablation or pacemaker treatment but is not referred, please explain why:

**Comments & drug therapy prescribed (optional):**

**Heart Failure & Ventricular Dyssynchrony Evaluation**

(please tick all that apply and attach ECG documentation for all ECG related parameters)

| Heart Failure | NYHA Class | Sinus rhythm QRS duration = | Left ventricular ejection fraction = |
|---------------|------------|-----------------------------|-------------------------------------|
| Stage B       | Stage C    | Stage D                     | Class I                             | Class II                             | Class III                             | Class IV                              |
|               |            | ms                          | %                                   |                                     |                                      |                                       |

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White copy- Medtronic  Yellow copy- Patient  Pink copy- Physician
## PANARhythmia and Heart Failure Registry

### Physician Case Report Form

| Patient ID | Page 02 of 02 |
|------------|---------------|

#### Left bundle branch block

#### Right bundle branch block

#### Neither

**Other, please specify:**

- [ ] Patient referred to cardiologist for further evaluation & treatment
  - [ ] Yes
  - [ ] No
  - If patient is potentially suffering from heart failure amenable to treatment by Cardiac Resynchronization Therapy* but is not referred, please explain why:

- [ ] Comments & drug therapy prescribed (optional):

* NYHA III, IV patients, Sinus rhythm QRS width > 120 ms & LVEF < 35% could benefit from CRT

### Sudden Cardiac Arrest Risk Evaluation

(please tick all that apply and attach ECG and echo documentation as specified in the footnote)

- [ ] Cardiac arrest survivor due to ventricular fibrillation/ventricular tachycardia

- [ ] Sustained ventricular tachycardia

- [ ] Prior MI (> 40 days ago), EF < 40%, non-sustained ventricular tachycardia

- [ ] Prior MI (> 40 days ago), EF < 35%, NYHA Class II, III

- [ ] Prior MI (> 40 days ago), EF < 30%, Stage B heart failure

- [ ] Non-ischemic dilated cardiomyopathy with EF < 35%, NYHA Class II, III

- [ ] Long QT syndrome

**Other, please specify:**

- [ ] Patient referred to cardiologist for further evaluation & treatment
  - [ ] Yes
  - [ ] No
  - If patient is at high risk for Sudden Cardiac Arrest and a potential candidate for ICD Therapy but is not referred, please explain why

- [ ] Comments & drug therapy prescribed (optional):

---

1- ECG documentation required, 2- ECG & Echo documentation required

### Disease etiology  

(please tick all that apply)

- [ ] Coronary artery disease

- [ ] Rheumatic valvular heart disease

- [ ] Degenerative disease

- [ ] Congenital heart disease

- [ ] Iatrogenic disease

**Other/Comments, please specify (optional):**

### Referral Status

(please complete sections B,C for all referred patients)

- [ ] A. Patient referred to cardiologist for further evaluation & treatment?  
  - [ ] Yes
  - [ ] No

- [ ] B. Has the patient information been included in the Referred Patient Log?  
  - [ ] Yes
  - [ ] No
  - If not, Please explain why:

- [ ] C. Patient counseling on potential disease & interventional treatment option (please tick all that apply)

  - [ ] Discussion with patient conducted

  - [ ] Disease & therapy brochure provided

  - [ ] List of internet websites providing information about disease & intervention provided

  **Other, please specify:**

  **If none of the above, please explain why:**

---

**Date of signature**

**Signature of Physician**
# Patient Referral Form - Panarrhythmia & Heart Failure Registry

| Patient ID |
|------------|

Patient has been referred for possible treatment with:
- [ ] Pacemaker implantation
- [ ] Radiofrequency ablation
- [ ] Implantable defibrillator implantation
- [ ] Cardiac Resynchronization Therapy

Patient has been counselled on potential disease and treatment option [ ] Yes  [ ] No

Patient has been provided with the Patient Copy of the RP CRF [ ] Yes  [ ] No

Patient has been instructed to present a copy of the RP CRF, ECG and Echo reports to the implanting cardiologist upon consultation [ ] Yes  [ ] No

Date Referred: [ ]  [ ]  [ ] 2  [ ]  [ ] 0  [ ]

Cardiologist details (Optional)
Name: 
Address: 
Telephone: Office: Mobile:

Date of signature: [ ]  [ ]  [ ] 2  [ ]  [ ] 0  [ ]

Signature of Physician

[ ]  [ ]  [ ]  [ ]  [ ]  [ ]  [ ]

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Pink copy: Physician
## Appendix C. Interventional Cardiologists Case Report Forms (IC CRF).

### Administration

**Name of physician**

**Name of cardiologist**

**Patient referral & consultation status at the time of completion of this form**

- [ ] Not-referred
- [ ] Referred but did not consult
- [ ] Consulted on

**Patient records evaluated to complete this form**

- [ ] Physician CRF
- [ ] ECG
- [ ] Echo

### Additional Tests Recommended / Performed

- Tilt-table Test
- Implantable Loop Recorder
- Tread Mill Stress Test
- Echocardiographic Testing
- Holter Monitoring
- Electrophysiology Study
- External Event Recorder
- Angiography
- Other, please specify

### Key Results from Tests:

#### Diagnosis

| Bradycardia & Conduction Defects | Supraventricular Tachyarrhythmia | VT & SCA Risk | Heart Failure |
|---------------------------------|---------------------------------|---------------|--------------|
| Sinus Node Dysfunction | Atrial fibrillation | SCA survivor | Stage |
| 3˚ AV Block | Atrial flutter | Sustained VT | NYHA Class |
| 2˚ AV Block Type 2 | Atrial tachycardia | Prior MI, EF < 40 %, NSVT | Sinus Rhythm QRS Width |
| 2˚ AV Block Type 1 | Paroxysmal SVT | Prior MI, EF < 35 %, NYHA Class II, III 1/2 | LBBB |
| 1˚ AV Block | Other, please specify | Prior MI, EF < 30%, Stage B heart failure | RBBB |
| Chronic AF with brady | Other, please specify | Non-ischemic DCM, EF < 35 %, NYHA Class II, III | IVCD |
| Carotid Sinus Syndrome | | Long QT syndrome | Narrow QRS |
| Other, please specify | | Other, please specify | |

LVEF %
PANARhythmia and Heart Failure Registry

Cardiologist Referral Form

Potential Therapy Requirement

- No interventional therapy required
- Single chamber pacemaker for bradycardia
- CRT-P for heart failure
- RF ablation for VT
- Other, please specify

- ICD therapy for SCA prevention
- Dual chamber pacemaker for bradycardia
- CRT-D for heart failure
- RF ablation for SVT

Disease etiology (please tick all that apply)

- Coronary artery disease
- Rheumatic valvular heart disease
- Degenerative disease
- Congenital heart disease
- Iatrogenic disease
- Other, please specify

- Hypertension
- Infectious disease
- Idiopathic
- Primary electrical disease
- Unknown etiology

Comments on further evaluation/treatment course and patient potential risk status provided as feedback for physician

- High Risk
- Medium Risk
- Low Risk

Date of signature: 20

Signature of cardiologist:

White copy: Medtronic

Yellow copy: Patient

Pink copy: Physician
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