Original Article

A survey of cardiac implantable electronic device implantation in India: By Indian Society of Electrocardiology and Indian Heart Rhythm Society

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ABSTRACT

Background: There is limited data regarding the demographics and type of cardiac implantable electronic device (CIED) in India.

Aim: The aim of this survey was to define trends in CIED implants, which included permanent pacemakers (PM), intracardiac defibrillators (ICD), and cardiac resynchronization therapy pacemakers and defibrillators (CRT-P/D) devices in India.

Methods: The survey was the initiative of the Indian Society of Electrocardiology and the Indian Heart Rhythm Society. The type of CIED used, their indications, demographic characteristics, clinical status and co-morbidities were collected using a survey form over a period of 1 year.

Results: 2117 forms were analysed from 136 centers. PM for bradyarrhythmic indication constituted 80% of the devices implanted with ICD’s and CRT-P/D forming approximately 10% each. The most common indication for PM implantation was complete atrio-ventricular block (76%). Single chamber (VVI) pacemakers formed 54% of implants, majority in males (64%). The indication for ICD implantation was almost equal for primary and secondary prevention. A single chamber ICD was most commonly implanted (65%). Coronary artery disease was the etiology in 58.5% of patients with ICD implants. CRT pacemakers were implanted mostly in patients with NYHA III/IV (82%), left ventricular ejection fraction <0.35 (88%) with CRT-P being most commonly used (57%).

Conclusion: A large proportion of CIED implants in India are PM for bradyarrhythmic indications, predominantly AV block. ICD’s are implanted almost equally for primary and...
1. Introduction

Advances in the management of arrhythmias and heart failure have resulted in increasing use of cardiac implantable electronic devices (CIEDs), that include permanent pacemakers (PMs), implantable cardioverter defibrillators (ICDs), and cardiac resynchronization therapy (CRT) pacemaker (CRT-P), or with defibrillator (CRT-D). To date, there have been no large, multi-center data available in the use of these devices in India. This survey was undertaken to understand the use, indications, demographics, clinical characteristics and co-morbidities of patients undergoing CIED implants. It is hoped that these initial data would help to improve upon building better databases of device implantations in India.

2. Methods

This survey was a joint initiative undertaken by the Indian Society of Electrocardiography (ISE) and the Indian Heart Rhythm Society (IERS). The survey was conducted for 1 year, from April 1, 2012 up to March 31, 2013. A device survey form was circulated amongst implanting cardiologists, who volunteered to be a part of the survey. The details collected included the type of implant (PM, ICD, CRT-P/D), type of device (single chamber/dual chamber) for PM and ICDs, indications for implantation, age, gender, New York Heart Association (NYHA) class, associated co-morbidities, left ventricular ejection fraction and whether it was a first implantation or replacement, and whether reused devices were used (Appendix 1). The forms were then submitted to an independent clinical research organization for analysis. Results of continuous measurements are presented as Mean ± SD (Min–Max) and results of categorical measurements are presented as number and percentage (%).

3. Results

A total of 2117 survey forms were collected from 136 centers (Fig. 1) across India from implanting cardiologists.

Bradycardia pacemakers constituted the major bulk of the CIED implants in India. Amongst the 2117 survey forms,
bradycardia pacemakers were used in 80% of patients. 10% were ICD implants and 10% were CRT-P/CRT-D. The age distribution per decade of life revealed a maximum (31%) device use in the 6th decade of life, with 22% and 20% in the 5th and 7th decades, respectively. The gender distribution for overall CIED implants was 64% males and 36% females. The gender distribution (male:female) in bradycardia pacemakers, ICD and CRT was 65:35, 85:15 and 70:30, respectively.

**Bradycardia pacemakers.** The commonest indication was complete atro-ventricular block, 76%. The device type distribution is shown in Fig. 2. Single chamber device use was 54%. Amongst dual chamber pacemakers, DDDR pacemakers were used in 34% and VDD pacemakers in 11.5% of patients. Most pacemakers were first implants (86%) with 14% being replacements or upgrades. No re-used bradycardia pacemakers were implanted. 56% were in NYHA class II and 31.1% in NYHA class I. Most (85%) patients had LVEF > 0.45. The commonest co-morbidities in patients with PM implantation were hypertension (28%), diabetes (15.6%), and coronary artery disease (CAD, 13.5%). In 27.5% of patients no co-morbidities were noted.

**ICD**. Single chamber ICD was most frequently (65%) used for prevention of sudden cardiac death from ventricular tachyarrhythmias. Primary prophylaxis use of ICD was seen in 52.5%. The commonest etiology for ICD use was CAD (58.5%), followed by idiopathic dilated cardiomyopathy (31.8%), hypertrophic cardiomyopathy (6%), and channelopathies (3.7%). First implantation of ICD was in 82.7% and remaining 17.3% were replacements or upgrades. NYHA class II and III were noted in 48.6% and 30%, respectively. LVEF was < 0.35 in 72.5% of patients. Re-used ICDs were implanted in 2% of patients.

**CRT devices.** CRT-P was implanted in 57% of patients and CRT-D in the remaining 43% patients. First implant CRT was in 78%; 22% were either replacements or upgrades in this group. The vast majority of these patients were in NYHA III (71%) and NYHA IV (11%). Only 18% were in NYHA II. The QRS width was >150 ms in 46% and between 120 and 150 ms in 50% of patients. The LVEF was < 0.35 in 88% of patients (Fig. 3). Idiopathic DCM was present in 53% of patients with bi-ventricular pacing devices.

4. Discussion

The Eucomed data on total number of CIED units sold in India in the year when this survey was conducted was about 37,000. This survey, therefore, captured data from nearly 6% of all CIED units implanted. The average age of patients undergoing CIED implants in India is almost a decade younger than the western world.

The use of CIED has remarkably increased, all over the world, in the last decade. In North America & Europe, CIED implants per million populations are very high at an average of 300 patients per million. In the Indian context, it is a meager 25 implants per million people. This is likely due to the high cost and self-payment in most patients; shortage of trained cardiologists to implant these devices and probably the more stringent use of these devices as only a life-saving measure and not for quality of life improvement. The last point is well highlighted by nearly 80% of bradycardia devices being for complete AV block and only 20% for sinus node dysfunction (affecting quality of life rather than longevity). The bradycardia indication for pacemaker use, is not a reflection on the etiology...
of bradycardia in India, but the preference of use for more malignant or life-threatening bradycardias. This is completely reverse of what is practiced in the western and other developed nations. Amongst the type of devices implanted, it is interesting to note that despite higher percentage of complete AV block and relatively younger population, most receive a single chamber pacemaker. This could be because of the cost (dual chamber pacemakers cost almost twice the single chamber pacemaker). Expertise of the operator also may be playing a role in not implanting the atrial lead. The VDD pacemaker seems to be underutilized. To offset the cost of dual chamber pacemaker, either a dual lead or a simple pass VDD lead should have been used more for AV block patients. This would help to maintain the AV synchrony and possibly lower the chances of pacemaker syndrome, atrial fibrillation, etc. However, this needs to be evaluated on a longer follow-up in present times. The clinical characteristics of bradycardia pacemaker patients seem to be more or less similar to what is seen in the rest of the world.

The overall number of ICD implants amongst all CIED was low at 10%. This again is in contrast to the western countries. The reasons could be many, including the cost and few electrophysiologists to implant these devices. However, there is possibility of a referral bias, and the treating cardiologist or physician does not perceive the benefit of these devices. More than 50% of patients with ICD implants are for primary prophylaxis. This seeming paradox in cost-sensitive India can be partly explained by the implanters, i.e. electrophysiologists’ (EPs) perspective. It is likely that only those patients who can afford these devices are referred to the EPs and the latter implement the western guidelines more frequently, which is acceptable to the self-paying, affording patient. This also partly explains the relatively higher number (almost one-third) of ICDs implanted being dual chamber, not discounting the fact that some of them may have additional pacing requirements and hence the need for dual chamber ICDs. Nearly 60% of ICD implants were for patients with CAD and three-fourths of the patients had EF < 0.35 and vast majority were in NYHA II. This is reflective of appropriate patient selection by the implanters.

In the CRT devices implantation, the dominant population was dilated cardiomyopathy with LVEF < 0.35 and in NYHA class III, again suggesting appropriate patient selection. However, CRT-D use was 43%, a relatively higher number as compared to Europe. This might be again because of out of pocket payment for these expensive devices; hence, only those affording (in the overall CRT group) accept the choice of CRT-D.

One of the important social messages from this survey is that predominantly men undergo CIED implantations. The gender gap gets more striking with expensive devices like ICD and CRT. In India, where there is negligible government funding for CIED and poor coverage for health insurance, out of pocket spending is abysmally poor for women for expensive treatment. For the implanters, it should be emphasized that it is women with dilated cardiomyopathy who respond more favorably to CRT.

5. Limitations

This was a voluntary survey of relatively small number of total CIED implants in India. Though a cross-sectional representation is likely across socio-economic strata within India, the random sample collection might introduce some bias. Being a one-time survey, only limited information was captured.

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Conflict of interest

The authors have none to declare.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.ihj.2015.06.037.

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