

The National Survey of Cardiac Pacemakers and Cardioverter Defibrillators

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Abstract

Background: Permanent pacemakers provide effective relief of symptoms and are life-saving in patients with symptomatic heart block. Implantable cardioverter defibrillators (ICD) are also increasingly recognized as life-saving tools in various groups of patients with malignant ventricular tachyarrhythmias.

Methods: As part of the "world survey on pacemaker and ICD implantations", a survey of all device implantations in Iran during the year 2001 was performed. Data was collected and cross-checked through three sources i.e. direct contact with implanting physicians, pacemaker companies and the governmental pacemaker distributing body.

Results: During the year studied, 1635 patients received permanent pacemakers. 88% were new implants at an estimated rate of 24 per million population. The mean age of patients was 65 years and 56.2% were male. 40 cardiologists and 19 surgeons implanted the pacemakers at 27 centers throughout the country. Complete heart block was consistently the most common indication at all centers (mean 56.1%), sick sinus syndrome being the next most common one (mean 20.8%). 69% of the pacemakers were single chamber pacemakers. Transvenous insertion of bipolar steroid-eluting passive fixation leads was the predominant practice at most centers. A total of 60 ICDs were implanted at 7 centers by 9 cardiologists. 45% of ICD implants were dual chamber devices.

Conclusion: The survey is the only one available right now and provides useful information about the prevailing pacemaker and defibrillator implantation practice in Iran. Future surveys would be facilitated if a standardized implant registry such as that used in Europe were established in this country.

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Introduction

Pacing is a field of rapid clinical progress and technologic advances. Pacemakers and implantable cardioverter defibrillators (ICD) are increasingly recognized as efficient tools for the management of cardiac rhythm disorders. Clinical progress

in the 1990s have included the refinement of indications for pacing as well as the use of pacemakers for new, non-bradycardiac indications, such as the treatment of cardiomyopathies and congestive heart failure.¹⁻³ Important

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published data and studies are shedding new lights on issues such as pacing indications and pacing mode selection, and they have influenced practice patterns significantly.⁴ Pacemaker surveys are reported from countries around the world and some countries are conducting nationwide surveys on a regular basis.⁵⁻⁷ No reliable data have, however, been available about the implantation rates for devices or the prevailing implantation practices in Iran. Unfortunately, the only reported data about this country contains inaccurate and contradictory data.⁷ An accurate and comprehensive survey could provide useful insights into trends and differences in pacemaker and defibrillator practices. Rigorous and expert analysis of the available data can also provide the decision makers with helpful guidelines that improve the effectiveness of care, optimize patient outcomes, and impact the overall cost of care favorably by focusing resources on the most effective strategies. As part of the World Survey on Pacemaker and ICD Implantation, a survey of all device implantations in Iran during the year 2001 was performed. This data was presented along with the data collected by other investigators from other parts of the world at XII World Congress on Cardiac Pacing and Electrophysiology, Feb. 2003 and it was published at PACE journal at July 2004.⁸

Methods

During the year 2001, all hospitals, university or private, involved in pacemaker implantation were identified. A list of all cardiologists active in pacemaker implantation was compiled. Those with sufficient interest in pacemaker and ICD to invest time and effort necessary to gather the necessary data were selected from each center and/or city and contacted. A response was obtained from 9 physicians (36%), for whom the survey questionnaire form was sent. At some areas physicians involved in pacemaker programming and follow-up were summoned for help. The questionnaire soliciting 26 pieces of information was a modification of the XIIth World Congress: World Survey form (kindly provided by Dr. Harry G. Mond) for collecting the whole country data.

Information was also obtained independently from the representatives of the two pacemaker manufacturers providing pacemaker and ICD devices (Medtronic and St. Jude) as well as a governmental agency (Exchange Board of Trustees) that was the sole distributor of pacemaker and ICD devices to the governmental hospitals at the time. The data collected from the three sources of information were cross checked and verified.

The compiled data from the whole country are analyzed and reported. However, it should be pointed out that the results of a few high volume centers were different in some respects from the others and for some measured variables affected the whole data.

Results for pacemakers

Demographics

A total of 1635 pacemakers were implanted in the whole country of which 1439 (88%) were new implants. The number of new implants per million population was estimated as 24/million for the whole country but no estimates were possible for different regions of the country as implantation facilities were not available at all areas and patients had been referred to other centers. Overall, 56.2% of the patients were reported to be males with an average age of 65.4 years. Females (43.8%) had a similar average age of 66 years. Age distribution is depicted at Figure 1..

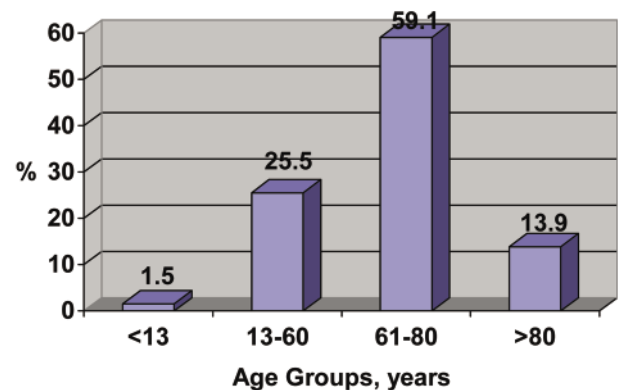


Figure 1. Distribution of age groups

Implanting centers

27 centers were identified as implanting pacemakers, though less than 5 pacemakers per year were implanted in 6 hospitals. 57% of pacemakers were implanted in Tehran.

One third of the centers were private non-governmental hospitals but they only implanted 9.6% of all the implants during that period.

A review of implanting physicians identified 59 doctors (40 cardiologists, 19 surgeons). 72.5% of implantations throughout the country were performed by cardiologists.

Median duration of admission varied greatly between the studied centers from 1 day to 11 days. For the whole country it was estimated to be 5 days.

Indications

Complete heart block was the most common indication at all centers (mean 56.1%) with sick sinus syndrome comprising the next most common one (mean 20.8%). Table 1 describes the mean proportion of indications for the whole country. Pacemaker implantation for newer indications (the last 3 groups of table 1) was reported only from a few centers.



Table 1. Indication for initial implant

Group	Description	%
Unspecified	Unknown	4.2
AV Block	1°/ 2° heart block	15
	Complete heart block	56.1
Bundle Branch Block	All combinations (No AV block)	2.7
Sick Sinus Syndrome	Bradycardia	10.4
	Bradycardia/ tachycardia	5.8
	Chronic AF + bradycardia	4.6
Carotid Sinus/ Neurocardiogenic syncope		0.2
AV Ablation		0.5
Cardiomyopathy	Hypertrophic	0.4
	Congestive (biventricular)	0.1

Pacemaker types

Great divergence of practice in different centers was evident at this area. VVI/VVIR was the only mode at initial implant at some centers, while it comprised less than 50% of new implants at the others (39% at one center). For the whole country, 31% of all implants were dual chamber pacemakers (including single pass VDD) even though this was greatly influenced by the results of a few centers. Data

About pacemaker modes are presented in table 2.

Table 2. Proportion of pacing modes at initial implant

Pacing Mode	%
VVI	28.7
VVIR	40.3
AAI/ AAIR	0
VDD	17.2
DDD	2.1
DDDR	11.7

Pacing leads

There was not much difference in practice patterns in this area. For the whole country, transvenous leads were used in 97.8% and Epicardial leads in 2.2%. Other data about pacing leads are summarized in table 3.

Table 3. Characteristics of pacing leads

	Atrium	Ventricle
Lead Type		
Transvenous (%)	97.8	95.2
Epi-myocardial (%)	2.2	4.8
Electrode Configuration		
Bipolar (%)	87.4	79.4
Unipolar (%)	12.6	20.6
Lead Fixation		
Active fixation (%)	12.6	4.2
Passive fixation (%)	87.4	95.8
Electrode		
Steroid-Eluting (%)	95	95
Non-steroid (%)	5	5
Lead Insertion		
Introducer (%)	99.4	98.6
Venous cut down (%)	0.6	1.4

Lead Extraction

14 cases were reported countrywide, all being extracted by traction method.

Results for ICDs

60 ICDs were implanted during the year 2001.

Devices were implanted at 7 centers (4 university and 3 private hospitals) by 9 cardiologists. 45% of implants were dual chamber devices and 5% were ICDs with biventricular pacing capabilities. All were new implants.

Discussion

Little data had been available on pacemaker and ICD implantation practices in Iran. This survey was the first attempt at collecting genuine and reliable information from the whole country. Although we had a low response rate from implanting physicians (36%), the data was collected and verified from other sources to ensure the collection of comprehensive and reliable information. The comparison of this data with that of other countries can be useful for elucidating the current obstacles and drawbacks in this life saving therapeutic field and to be optimistic, can be used by policymakers to implement future strategies aimed at better provision of health care for the community.

Our nationwide rate of 24 new implants per million population was much lower than what was reported from most developed countries (median of 283/million in

Europe)⁷⁻¹⁰ and may be indicative of lack of access to medical care or lack of knowledge in the medical community about indications for pacemaker implantation. The younger age of our population may, on the other hand, have played a role. This is also reflected in a lower proportion of our patients at the above-80 age group (14%) vs. most developing countries (Japan 20%, Australia 25%, Canada 28%).⁷

Age may also be a reason why the most common indication for pacemaker implants in virtually all surveyed areas was reported to be complete heart block (average 56%). Sick sinus syndrome, increasing in incidence with advancing age, is a more common cause in many other parts of the world.⁹ Other causes may be under-detection or fewer tendencies to implant pacemakers in milder cases of sick sinus syndrome.

An interesting difference with the data of other countries is in the near zero incidence of single chamber atrial pacemakers and a proportionally high rate of implantation for single pass VDD pacemakers (average 17%). The latter figure is among the highest reported in the world.⁷ VDD mode was the one chosen for 34% of implants at one of the high volume centers. In appropriately selected cases single pass VDD pacemakers may be a suitable, less costly alternative to DDDR devices.¹¹ On the other hand, the high proportion of VDD implants accompanied by a near zero rate of AAI/AAIR pacemaker implants may reflect a lack of experience in atrial lead placement or lack of self-confidence in operators.

Inappropriate selection of the cases for VDD mode and failure to check for an adequate atrial sensing may end up in a pacemaker working practically in VVI mode with its known adverse consequences. A low rate of implantation of AAI/AAIR pacemakers may also imply a concern over long-term safety with the possible emergence of complete heart block.

A concerning issue is, however, the low proportion of physiological pacing (VDD or DDD/DDDR) at many implanting centers. VVI/VVIR was the only mode implanted at 7 centers and comprising over 80% of implants in 6 others. Although the survival advantage of physiological pacing is questioned,¹² a higher incidence of atrial fibrillation, congestive heart failure and stroke is reported with VVI pacing in several large trials.¹³⁻¹⁵ Various presentations of pacemaker syndrome may also occur in 20-60% of patient with VVI/R pacing and the necessity for an upgrade or reprogramming to DDDR is reported in 26% of cases in some trials.¹⁶ Cost problems appear to play a role. It looks, however, that unfortunately some physicians who refer patients for pacemaker implantation and some of those who implant them, are unaware of the advantages of physiological pacing systems and/or may not be experienced in implanting them.

An analogous problem lies in deciding when to implant an ICD or even deciding between a pacemaker alone versus a cardioverter defibrillator with pacing capabilities for patients with the substrate for the development of a malignant

ventricular tachyarrhythmia. Rates of ICD implantations in this country are among the lowest reported in the world⁷ and the greatest problems appear to be both in financial allocations and lack of knowledge in the medical community.

The decision about the type of pacemaker or ICD and various programming details may also be a tough one and may have a great impact on patient outcome, both in terms of mortality and quality of life.⁴ It is anticipated that these decisions will become even more compelling as the field advances and implantation techniques look easier to learn. Paradoxically, the modernization of implant and monitoring techniques will also bring up more implanters who are not electrophysiologists. Many of these individuals have an inadequate level of training or Commitment to the field to make correct diagnostic and therapeutic decisions, or to provide adequate surveillance, programming and follow-up for the patients in whom devices are implanted.

Lack of facilities and expertise for lead extraction in this country is an embarrassing issue that needs careful scrutiny. Everybody practicing in the field has encountered patients operated on several times for pacemaker infections, still carrying extruded leads or generators along with scars from the previous palliative procedures. Lead extraction is a demanding procedure that needs the necessary equipments as well as experience with an adequate case load. It is the responsibility of referral university hospitals to gather the required facilities and expertise for this costly service and financial incentives are not supposed to direct their management policies. Unfortunately, this does not appear to be the case.

So as usually happens in medicine, it is left to the physician to be the primary one caring for his patient. In this context, it means that the physician, independent of financial, bureaucratic, logistical, or any other extraneous factors must decide which patients need pacemakers or ICDs and what kind they should get. Education is also the key; that is, doctors who make this decision must have an in-depth understanding of the technology, its limitations, and its applications. They must also be aware of the clinical trial data that are relevant to the issue, acknowledging that trial data do not always exactly correlate with the patient under consideration and that "extrapolation is a way of life". When they don't know, they have to consult more knowledgeable colleagues for guidance. It is well established with coronary interventional procedures but sometimes forgotten in pacemaker and ICD fields that only a high level of education, training and practice will bring up the necessary competence and guarantee a favorable outcome.¹⁷ The increasing involvement in pacemaker insertion and follow-up by electrophysiologists should curtail the problem, although definitive data to prove better use by this "subspecialized" group are yet to emerge.

A survey is ongoing to collect the data for the year 2005, both for Iran and the other countries of the world but it will not be available until the year 2007. The current data is the



only one available right now and despite being published worldwide, in summary and along With the data of the other countries, had not been published in detail before. During the following years some important changes may have occurred. A great achievement has been made in changing the view of the cardiology community toward the pacemaker and electrophysiology field from a far-fetched, undesirable, complex and complicated procedure to a more easily understood and well-desired one with a high rate of success and nil rates of complications. Many centers have now developed or are willing to develop the necessary electrophysiology settings and many cardiologists are now interested in getting subspecialty training in this field. Devices are more frequently implanted by trained cardiologists than surgeons and this will hopefully have an impact on patient selection, appropriate device selection and procedure outcomes. It looks that physiologic pacing systems are more frequently implanted. The implantation of biventricular devices appear to have especially grown markedly and more ICDs are being implanted. Implantation practices regarding lead selection, site of access etc. also appear to have changed somewhat but we should wait for the results of the year 2005 to make firm conclusions. We hope that when the data for the year 2005 are ready, their comparison with the current data and the study of the trends would pave the way for further progress in the future.

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