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# CSI/IHRS practice guidelines on follow-up of patients with permanent pacemakers

## A Cardiology Society of India/Indian Heart Rhythm Society task force report on practice guidelines on follow-up of patients with permanent pacemakers

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### 1. Introduction

Implantation of a permanent cardiac pacemaker is a frequently used therapeutic modality. It has been estimated that approximately 25,000 pacemakers were implanted in India in 2011. Over the last five decades, cardiac pacemakers have evolved from single chamber non-programmable devices to dual chamber devices with extensive programmability. The implantation of the device is only the initial step in the lifelong management of the patient with a pacemaker, and long-term follow-up is vital not only for the safety of the patient but is also the key to optimal utilization of the pacing system. However in most places in our country, patients with implanted pacemakers are usually seen only annually and often only toward the end of pacemaker battery life.

Due to the increasing number of pacemaker implants across India, the number of patients being admitted with the general physicians, having a pacemaker implanted or needing one has increased significantly. As many of these patients may be admitted with other medical problems, medical specialists are also now increasingly involved in their

management. Although implantation and management of pacemakers fall primarily under the realm of the cardiologist, it is imperative that the general physicians also be conversant with some of the issues which impact the overall management of the patient.

This document will deal with a broad overview of the elements of a follow-up program but will not attempt to describe various pacemaker-timing cycles, analysis of pacemaker ECGs or the procedure of identification or management of specific pacemaker-related troubleshooting.

### 2. Goals of an optimal pacemaker follow-up and surveillance program (Table 1)

The implementation of an appropriate follow-up program requires trained personnel, a structured set of procedures and creation of a record and reporting system. Ideally, this data should be capable of being incorporated into a national database on pacemakers. Identification and management of problems and reporting of device-related issues to a specific

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**Table 1 – Goals of pacemaker follow-up.**

- Optimize pacing system function to meet the patient's clinical need
- Optimize the patient's quality of life and minimize fear and anxiety
- Maximize pulse generator longevity while maintaining patient safety
- Identify and correct abnormal pacing system behavior (including abnormalities due to the generator, lead/s or due to disease in the patient or evolution of his clinical condition)
- Identify pulse generators approaching end of battery service or leads needing replacement and to organize pacing system replacements in a timely, elective and non-emergent manner
- Identify patients readily and initiate appropriate follow-up in the event of recall or advisory

authority, as well as dealing with device-related advisories and recalls are other elements of a follow-up program.

### 3. Personnel, infrastructure and resources

#### 3.1. Personnel

The program must be led by a consultant cardiologist with a special interest and demonstrated competence in pacing. The lead consultant must assume responsibility for the program and for the delineation and delegation of responsibility as well as the conduct of audit and quality maintenance of the program. Fellows in cardiology or cardiac electrophysiology can participate under supervision. At present no legal regulatory framework or formal recognition of the role of paramedical personnel (physician assistants, nurses, technicians, etc.) exists in India and as such, any role played by them must be under direct supervision of a responsible physician. The role of the Industry Employed Allied Professional (even if qualified as a paramedical) has been defined and is limited to the provision of information and technical support, as well as updating the program on device-related advisories and recalls, always under the direct supervision of a responsible physician. Specifically, the practice of using the services of Industry Employed Allied Professionals for long-term direct technical support for routine follow-up is not desirable.

#### 3.2. Infrastructure

Most pacemaker follow-up in India occurs in the setting of an institution based clinic with direct interaction between the physician and the patient. Other methods such as transtelephonic monitoring, remote monitoring using devices located in the patient's home linked to a central receiving station or other forms of remote monitoring or telemedicine are not widely used. It is advisable to have a specific area in the hospital earmarked specifically for the pacemaker follow-up clinic so that the evaluation can be done in a focused and systematic manner and also storage of equipment, programmers and records can be conveniently achieved.

#### 3.3. Physical resources

Physical resources required in a pacemaker follow-up clinic is listed below:

1. Resuscitation equipment including defibrillator (external cutaneous pacing available) and drugs (while resuscitation may be infrequently performed, the availability of the equipment is mandatory)
2. Continuous ECG display monitor and multichannel ECG recorder with real time rhythm recording
3. At least one programmer for all pacemakers implanted in the region
4. Technical information on the behavior of all available implantable pulse generators and leads
5. Contact telephone numbers for all relevant manufacturers
6. Sterile equipment to manage wounds
7. Record system (and preferably a computerized database)

Other resources which should be accessible include, but are not limited to the following:

1. Facilities for fluoroscopy and X-ray
2. Ambulatory ECG monitoring
3. Exercise ECG testing system
4. Tilt test facility
5. Echo–Doppler evaluation
6. EP laboratory
7. Operating room or cath lab where implants or revision procedures can be done at short notice
8. Receiving equipment for transtelephonic or remote monitoring
9. Facility to admit patients on an urgent basis

### 4. Record maintenance

Record maintenance is a key element of pacemaker follow-up. Ideally both hard copies as well as an electronic version of the data should be maintained. The patient should be provided with not only the data pertaining to the implantation but also with a copy of all relevant follow-up data including programming changes etc. The records should be available round the clock. The important information that should be present in the record is listed below:

- Demographic data on the patient (name, age, address telephone number or other means of contact, next of kin or alternative way of contacting a patient)
- Complete diagnosis, including details on all other co-morbid conditions, especially those likely to influence cardiac rhythm
- Pacemaker operative record and record of previous procedures
- Manufacturer, model number and serial number of all implanted hardware
- Records of data from each follow-up visit including programmed setting, telemetry threshold evaluations and rhythm strips

- Patients clinical evaluation (symptoms and findings of focused clinical examination including inspection of the pacemaker site)
- Current medications
- Documentation of hardware advisory or recall, or any surgical complications

## 5. Frequency of follow-up visits

The frequency of follow-up varies from the early post-implant phase, through the maintenance phase and then a period of intensified follow-up toward the projected elective replacement of the pulse generator and is influenced by a variety of factors listed below:

### 5.1. Patient-related considerations

- Clinical indication for pacing and co-morbid conditions
- Patient dependency on pacing
- Stability of rhythm and cardiovascular symptoms and status
- Stimulation threshold – high/unstable or low and stable
- Patient's ability to recognize and respond to changes in clinical status and ability to reach clinic rapidly

### 5.2. Pacer system-related considerations

- Known reliability of the implanted pacing system (lead/s and pulse generator are considered independently)
- How long the patient has had the pacemaker (lead/s and pulse generator are considered independently)
- Programmed parameters (higher outputs = shorter time from elective replacement time to end of service)
- Type of pacemaker (endocardial versus epicardial)
- Complexity of pacing system
- Application of cardioversion, electrocautery or defibrillation or other event causing reset
- Age of patient (generally more frequent for pediatric patients)

## 6. A follow-up schedule should include as a minimum the following

### 6.1. Early assessment

Within 72 h of implantation, the main purpose of early post-implant assessment is for inspection of the operative site and to confirm satisfactory pacemaker system function. Most patients are now being discharged within 24 h of the implant and at discharge patients should be reassured about pacemaker function and provided with an identification card with details of the pacing system and the physicians contact details.

### 6.2. Early surveillance

2–12 weeks post-implantation. Usually the capture threshold shows a slight rise within 2–6 weeks of the implantation followed by a decrease and then a chronic plateau value. Hence a follow-up visit with the cardiologist at approximately 12

weeks time allows output reprogramming of the pacemaker settings to optimize safety margin and reduce battery drain. Sensing function should be assessed and diagnostics reviewed and programming fine-tuned. Ensure that the pulse generator site is healthy or plan action in the event of evidence of erosion or infection. Reinforce patient education regarding activities and clarify patient concerns.

### 6.3. Annual follow-up

Thereafter till a period when the battery can be expected to deplete significantly or till about 7–8 years after the implant (depending on the type of pacemaker). A focused clinical assessment of the patient as well as documentation of the underlying intrinsic rhythm should be done. Measurements of lead impedance, capture thresholds, sensing safety margins, battery status and review of diagnostic data are essential. Review of appropriateness of programmed variables as well as assessment of any significant changes in measurements (e.g., of lead impedance, capture thresholds etc.) to be done to enable appropriate intervention if required. Evaluation of device site and lead course needs to be performed at each visit to detect late infection or pulse generator displacement.

### 6.4. Intensified follow-up period

Should be implemented when approximately 75% of expected battery longevity has been reached or when first indication of battery depletion occurs (in otherwise normal conditions) or at any time when an unexpected change in measurements (e.g., change in lead impedance or threshold) occurs. The specific behavior (change in magnet rate or pacing rate toward elective replacement or end-of life) should be available for all the devices on follow-up and should be available for a specific device in each patient's individual record (for ready reference). Pulse generator change (or lead revision) should always be done in a planned, elective and non-emergent manner as far as possible. Change of mode/upgrade of the system should be considered at the time of pulse generator change. Any need for surgical revision of the pocket as well as the need for any lead changes should be addressed at the time of planned pulse generator changes.

#### 6.4.1. At each visit, the pacemaker follow-up protocol should include the items in Table 2

History of syncope, presyncope or dizziness may not always be due to pacemaker malfunction; it may well be related to underlying cardiac disease or use of anti-hypertensive drugs; hence a detailed cardiovascular assessment and complete history of cardio-active drugs needs to be elicited in all patients. Excessive dyspnea or fatigue in the absence of underlying coronary artery disease, pulmonary disease or valvular heart disease may be the result of pacemaker syndrome or inappropriate pacemaker programming and should promptly be referred to the specialist cardiologist. Recognition of these symptoms is important to improve patients' overall well being by appropriate changes in pacing parameters. A twelve lead ECG with and without magnet placed over the pulse generator should always be recorded. An X-ray chest is also an integral part of all pacemaker follow-up and mainly helps in ascertaining the number of leads in place, the sites being paced and

lead position. When needed it may be complimented with fluoroscopy, especially to detect lead insulation defects or lead fracture. Comparison with post-implantation X-ray may also help in detection of lead displacement and migration.

## 7. Management of specific issues in patients with an implanted pacemaker

### 7.1. Tips for the physicians

Patients with pacemakers can undergo most routine investigations or interventional or surgical procedures safely.

Procedures where significant electromagnetic interference appears likely (e.g., use of electrocautery etc.) can usually be managed by the use of precautions to reduce exposure (use of bipolar cautery with short periods of usage and ensuring that the usage is not within the close vicinity of the device). In most other situations (lithotripsy, transcutaneous nerve stimulation etc.) the pacemaker can be programmed to a VOO mode during the procedure and reprogrammed after the procedure. Devices should preferably be interrogated after any procedure and appropriate reprogramming done.

Diagnostic radiography usually does not interfere with pacemaker function. In the case of therapeutic radiation,

pulse generator shielding or moving the pacemaker out of the field or radiation may be required.

MR imaging was considered contra-indicated in patients with pacemakers till recently, but now some pacemakers are available where MR imaging is possible (with certain conditions). Reference must be made to the specific instructions of the manufacturer to determine the type and nature of investigations permitted.

### 7.2. Central line placement

Insertion of central venous lines and pulmonary artery catheters requires special care in patients with implanted pacemakers. Subclavian venipuncture should be avoided ipsilateral to an implanted device because the needle has the potential to puncture or tear the insulation of indwelling leads, leading to device malfunction. Either a contralateral subclavian puncture or internal jugular venipuncture on either side is preferred. Care must also be exercised when floating pulmonary catheters are present. In passing through the right heart, the catheter might dislodge pacing leads, especially in the early post-implant period. This is chiefly a concern for passive fixation leads, especially left ventricular leads placed via the coronary sinus, which are particularly prone to dislodgement. In such patients, pulmonary artery catheters should be avoided if at all possible. Optimally, leads should be passed through the right heart under direct fluoroscopic guidance.

### 7.3. External cardioversion and defibrillation

Patients with implanted pacemakers, defibrillators can undergo external cardioversion or defibrillation in an emergency. During elective or emergent external cardioversion or defibrillation, the external paddles/electrodes should be placed as far distant from the permanent pacemaker in an *anteroposterior manner*, to avoid damage to the device from the external energy discharge. After external energy delivery, pacing thresholds may rise, leading to loss of pacing capture. Thus, whenever possible, the pacemaker should be interrogated before external energy delivery, and the pacing output should be increased for the procedure. After the procedure, the pacemaker should always be interrogated to ensure that device function and/or programmed parameters have not been altered.

### 7.4. Diagnosis of myocardial infarction (MI) in paced patients

Since most patients are paced from the RV, leading to an LBBB pattern on the ECG, criteria for diagnosing acute MI in presence of LBBB need to be applied. The diagnosis of inferior MI is made in the usual manner in patients with paced ECG's since LBBB does not interfere with the ST elevation in inferior leads (II, III and aVF).

However the following criteria need to be applied to diagnose acute anterior MI in the presence of LBBB:

- 1) ST-segment elevation  $\geq 1$  mm in leads with a positive QRS complex
- 2) ST depression  $\geq 1$  mm in leads V1–V3 (leads with a dominant S wave)
- 3) ST-segment elevation  $\geq 5$  mm in leads with a negative QRS complex

**Table 2 – Patient and device assessment.**

#### 1. Patient assessment

##### A. Items to determine in a cardiovascular history:

- Dizziness, syncope, palpitations, dyspnea, fatigue, angina
- Any significant clinical event (hospitalization etc.) since last visit
- Medication review

##### B. Items to determine in a focused physical examination:

- Heart rate and rhythm (ECG with and without magnet)
- Heart sounds, breath sounds, signs of cardiac failure
- Wound and site assessment

#### 2. Device assessment: items to determine in a device history:

- Time since implant of the lead/s and the pulse generator
- Previous hardware complications (e.g., advisory hardware, lead fracture, abandoned leads)

##### A. Data from available telemetry (varies with manufacturer and model)

- Programmed settings including last programmed date
- Battery status (cell impedance, voltage, energy, charge, current drain)

##### B. Check list of automatically available diagnostic data (varies with manufacturer and model)

- Percentage of pacing and sensing in each chamber
- Counter of ventricular arrhythmias and atrial tachycardia (using user – defined criteria for data collection)
- Lead impedance trends over time
- Capture and sensing thresholds over time

##### C. If not available automatically:

- capture and sensing threshold assessment

## 8. Management of pacemaker/pocket site

Pacemaker pocket infection can occur in the following three settings:

*Acute (within days to few weeks post-implant) infections* are rare, if adequate aseptic precautions have been taken during the implant. In the early post-implant period, slight superficial epidermal serous discharge or a minor stitch seroma can occur. These superficial infections are often successfully managed by aseptic cleaning and dressing with or without oral antibiotics. However deeper dermal pus collection which increase by squeezing the pacemaker pocket are enough to suggest pocket infection and should be referred to the implanting cardiologist. Small boggy and soft hematomas usually self reabsorb within 4–6 weeks and should be managed conservatively. *Needle aspiration should be avoided, as it more often tends to introduce infection.* Large, tense, painful hematomas are often seen in patients receiving concomitant oral anticoagulants; these may necessitate opening of one edge of the wound aseptically (especially if the hematoma is increasing in size), evacuation of hematomas followed by resuturing.

*More commonly, infections occur few weeks to months after the procedure,* presenting as erythema, induration and pain in the first 3–6 months leading to a subacute local abscess with serous/pus discharge. If left untreated, it may eventually erode through the skin with lead/device extrusion; less commonly, it may track internally to cause right heart endocarditis. Septic emboli from such an infected lead can occasionally embolise to the lung leading to unexplained pneumonia/pulmonary embolism. *Device infection can also occur months to years after the implantation,* especially in thin built and elderly patients, where the pacemaker gradually erodes through its subcutaneous pocket and becomes adherent to the overlying skin with subsequently infection and extrusion.

Hence important pointers toward a device-related infection are if:

1. The patient presents with PUO weeks to months after device implantation
2. The patient has recurrent unexplained episodes of pneumonitis
3. There is evidence of local infection at the pacemaker site

A transthoracic echocardiogram (and if needed a transesophageal echocardiogram as well) should be done in all cases to rule out right heart endocarditis in cases with gross pacemaker site infection and sepsis. As initial starting therapy, antibiotic coverage against (*Staphylococcus* and gram negative bacilli) is useful, since these are the most commonly isolated organisms in cultures from the local site. Though treatment with culture guided antibiotics and generator pocket debridement without hardware removal has been practiced, high failure rates with recurrent infections are common, especially in cases of extrusion of the pacemaker or the lead. In these cases, complete removal of the system, optimal antibiotic therapy followed by reimplantation, preferably from the contralateral side is the only effective solution.

Hence physicians treating such pacemaker-related infection should promptly refer such patients to the primary

cardiologist rather than persist in protracted course of antibiotics as a means to try and suppress the infection.

## 9. Advice regarding airport screening, use of mobile phones and other electronic equipment

It is now accepted practice to advise patients that while airport screening devices are likely to detect the pacemaker, *the device itself will not be adversely affected.* Patients should carry their device identification card for obtaining security clearance. Though patients can go through metal detectors without causing a pacemaker or cardioverter-defibrillator malfunction, patients may request and be granted permission to be scanned with a hand-held screening wand, or by a physical pat down.

Current cellular phones are very unlikely to interfere with pacemaker operation; patients need to observe certain broad precautions (a) maintaining a distance of at least six inches between the phone and the implanted device (b) holding the cellular phone to the ear opposite to the side of the implant (c) avoiding carrying the cellular phone in a pocket on the same side as the implanted pacemaker.

Most office and domestic equipment is unlikely to interfere with pacemaker operation if the equipment meets current electrical safety standards. Hence patients with current generation of pacemakers can safely use computers, electric typewriters, electrostat and fax machines and all types of household appliances (including microwave ovens) and power tools.

## 10. Patient death

In case of death of patient with an implanted device, it is recommended that the device be removed prior to cremation, because of the explosive potential of these devices pacemakers when heated and potential damage to the electric crematorium circuitry. In open cremation, the explosion can cause distress to the observers. It is imperative that consent of the relatives be sought in all such cases. Adequately completed death forms certifying the presence of a device and proactive questioning of the deceased's relatives by the crematoria staff about the presence of a pacemaker are important steps.

## 11. Stopping oral anticoagulation (OAC)/dual anti-platelet (DAPT) drugs prior to pacemaker implant

As a general rule, oral anticoagulants need to be stopped at least 48–72 h before the planned implant, change-over to intravenous unfractionated heparin or low molecular weight heparin as needed, and performing the implant once the INR is <1.5 are important in reducing the chances of post-implant hematomas. For patients on anti-platelet drugs, this is often an individualized decision making and there is no clear consensus about this. Aspirin is not known to significantly increase the number of implantation-related bleeds and may be continued if needed. Pocket hematomas are generally more common in patients receiving ICDs than those receiving pacemakers and amongst those on DAPT. Although previous

studies reported that DAPT increased the rate of implant-related bleeding complications, recent data suggest that treatment with DAPT does not increase the risk of major bleeding complications (e.g., tamponade, need for blood transfusions, hematomas necessitating pocket revisions or prolonged hospitalization) although minor complications (e.g., small self-resolving pocket hematomas, local ecchymosis etc.) are significantly more frequent. The use of electrocautery during the pacemaker implant to achieve perfect hemostasis is strongly recommended in these patients. As a general rule, stoppage of anti-platelet drugs should be decided on case to case basis and according to the indicated need of these drugs.

## 12. Management of pacemaker/lead advisories and recalls

Device manufacturers issue advisories or recalls when there is detection of a systematic failure mode affecting a large number of devices or patients. The existence of a patient registration system usually ensures that potentially affected patients can be identified by the manufacturers.

*Device recall/advisory has been classified as follows:*

- I. **High risk:** a reasonable probability that the device fault will cause serious adverse consequences or death
- II. **Moderate risk:** a reasonable probability that device fault will cause temporary or medically reversible adverse health consequences, or a remote probability of serious adverse consequences
- III. **Low risk:** device fault is not likely to cause any adverse consequences

The management of an advisory/recall consists initially of the classification of the recall. The pacing service then reviews the list of potentially affected patients and confirms the list received from the manufacturer with the clinic records. The hospital administration is notified and patients who are on

follow-up at other institutions are identified and the concerned institutions contacted and informed. Patients are contacted and counseled regarding the management plan and patient concerns addressed. The follow-up schedule is modified as necessary and the entire management plan and clinical interactions documented. Appropriate action as advised by the manufacturers which are acceptable to the patient are then implemented.

## FURTHER READING

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