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Cardiac Pacemakers: Indications, Choices and Follow Up

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INTRODUCTION

Therapeutic cardiac stimulation by permanent pacemakers has revolutionized the field of cardiology. Since the implantation of first internal pacemaker, pacing technology has evolved a lot, including reduction in size of pulse generator, increase in longevity and complexity of devices. Latest technology is Leadless pacing system.

Type of pacemakers: Current permanent pacing systems are of three types: Transvenous systems, Epicardial systems and Leadless systems. Pacing systems consist of two components: a pulse generator, which provides the electrical impulse for myocardial stimulation; and one or more electrodes (commonly referred to as leads), which deliver the electrical impulse from the pulse generator to the myocardium. Leadless systems contain pulse generator and lead in same unit.

Transvenous systems: The vast majority of contemporary cardiac pacing systems utilize transvenous electrodes (leads) for transmission of the pacing impulses from the pulse generator (which is implanted most commonly in the infraclavicular region of the anterior chest wall) to the myocardium. Transvenous leads are usually placed percutaneously or with a cephalic cut down. Transvenous leads, however, are associated with a non-trivial rate of long-term complications, including:

- Infection
- Venous thrombosis and resultant subclavian vein occlusion
- Lead malfunction
- Tricuspid valve injury (resulting in tricuspid regurgitation)

Epicardial systems — Epicardial cardiac pacemaker systems utilize a pulse generator with leads that are surgically attached directly to the epicardial surface of the heart. These systems have largely been replaced by transvenous systems for patients requiring long-term cardiac pacing, although there is still a role for the occasional patient with vascular access problems (eg, venous thrombosis, congenital anatomical variations, prosthetic tricuspid valve). The major role for epicardial pacing systems in current practice is for temporary pacing following cardiac surgery; such systems, however, are designed as temporary systems that must be removed within the first days to weeks following cardiac surgery.

Leadless systems: In response to the limitations of both transvenous and epicardial pacing systems, efforts have been made to develop leadless cardiac pacing systems. Initial leadless systems involved multiple components but were associated with high complication rates [1]. Subsequent leadless systems have utilized a self-contained system which includes both the pulse generator and the electrode within a single unit that is placed into the right ventricle via a transvenous approach[2].

Indications of Permanent Pacemaker Implantation[3]: Indications of permanent pacemaker implantations include

A. Sinus Node Disease: Permanent pacemaker is indicated in all patients with symptomatic sinus node disease, symptomatic chronotropic incompetence and symptomatic drug induced sinus bradycardia when discontinuation of the offending agent is not possible (Class I). In minimally symptomatic patients with sinus bradycardia and chronic heart rate less than 40 bpm while awake permanent pacemaker may be considered (Class IIb). In a patient with unexplained syncope pacemaker implantation may be considered if sinus rate is less that 40 /min or electrophysiological testing has documented sinus node disease (Class IIa).

B. AV nodal Disease: Permanent pacemaker implantation may be considered in all patients with complete heart block. Even if the patient is asymptomatic and ventricular heart rate is more than 40, permanent pacemaker implantation should be considered (Class IIa).Indication is stronger(Class I) if patients with complete heart block or advanced second degree AV block(blocking of 2 or more consecutive P waves with some conducted beats) have any of the following:

1. symptoms of bradycardia/ heart failure
2. bradycardia induced ventricular arrhythmias,
3. pause ≥ 3 seconds(≥ 5 seconds in presence of atrial fibrillation)
4. Ventricular rate less than 40
5. Cardiomegaly or LV dysfunction
6. Site of block is below AV node.
7. Any block developing after catheter ablation of the AV junction

If a patient with asymptomatic second degree AV block does not have the above criteria, EP studies should be done. If site of block is documented below the level of AV node by EP studies, permanent pacemaker implantation is recommended (Class IIa).

When a patient with first degree or second degree AV block has symptoms similar to those of pacemaker syndrome, permanent pacemaker implantation is reasonable (Class IIa).

C. Chronic Bifascicular Block: Pacemaker implantation should be considered in patients with chronic bifascicular block (irrespective of symptoms), if the bifascicular block is associated with intermittent complete heart block, advanced second degree AV block , Type 2 second degree AV block or documented alternating bundle-branch block(Examples are right bundle-branch block and left bundle-branch block on successive ECGs or right bundle-branch block with associated left anterior fascicular block on 1 ECG and associated left posterior fascicular block on another ECG). In a patient with chronic bifascicular block and syncope, if none of the above findings are documented, EP study may be considered and permanent pacemaker implantation is recommended ventricular tachycardia (VT) has been excluded(Class IIa). All chronic bifascicular block with markedly prolong HV interval (≥100 ms) or documented infra-His block should also be considered for permanent pacemaker.(Class IIa)

D. Post Myocardial Infarction : The criteria for permanent pacemaker implantation in patients with MI and AV block do not necessarily depend on the presence of symptoms. The long-term prognosis for survivors of AMI who have had AV block is related primarily to the extent of myocardial injury and the character of intraventricular conduction disturbances rather than the AV block itself. For all patients of AMI and persistent and symptomatic second- or third-degree AV block pacemaker should be considered (Class I indication). In an asymptomatic patient with persistent second- or third-degree AV block, permanent pacemaker implantation is Class I indication if the site of block is infra-His by ECG (alternating bundle-branch block) or by Electrophysiological study. In patients with transient advanced second- or third-degree AV block the indication remain same as in above mentioned group. Permanent pacing may be considered for persistent second- or third-degree AV block at the AV node level, even in the absence of symptoms (Class IIb).

E. Neuromuscular Disorders: Conduction system disease with progression to complete AV block is a well-recognized complication of several neuromuscular disorders such as myotonic muscular dystrophy, Kearns-Sayre syndrome, Erb dystrophy (limb-girdle muscular dystrophy),and peroneal muscular atrophy. In most cases the progression of conduction disease is unpredictable. Hence, any degree of AV block(including first degree AV block) and Fascicular Block is considered as Class IIb indication for permanent pacemaker implantation irrespective of symptomatic status. If such patient has third degree and advanced second-degree AV block, the scenario is considered as class I indication.

F. Carotid Hypersensitivity syndromes: Permanent pacemaker implantation should be considered in patients with syncope and documented ventricular aystole of more than 3 seconds on carotid stimulation (Class I).

G. Neurocardiogenic Syncope: In a patient with neurocardiogenic syncope permanent pacing may be considered if bradycardia documented spontaneously or at the time of tilt-table testing (IIb)

H. Pacing For Hemodynamic indication: Multisite pacing, also known as Cardiac resynchronization therapy(CRT) may be considered for patients with heart failure, LVEF<35%, QRS duration >120 ms and sinus rhythm. If the patient has a QRS duration of >150 ms, LBBB on ECG, NYHA Class II-IV on optimal medical therapy, CRT should be considered (Class I). If above mentioned patient has QRS duration 120 to 149 ms with LBBB or >150 ms with Non-LBBB(patient is Class III,IV on OMT), CRT may also be considered(Class IIa). Patient with LVEF<35% may require CRT irrespective of QRS duration if, Pacemaker is required for other indication with expected ventricular pacing >40% or the patient has atrial fibrillation and requires pharmacological blockade of AV node/ Av nodal ablation requiring 100% ventricular pacing(Class IIa).

I. Selection of Pacemaker Mode: In 1974 a combined task force from the American Heart Association and the American College of Cardiology proposed a three-letter code describing the basic function of the various pacing systems which was subsequently updated by a committee from the North American Society of Pacing and Electrophysiology (NASPE) and the British Pacing and Electrophysiology Group (BPEG). Currently this code has five positions and is known as NBG code for pacing (Table 1)[4]. The five positions are as follow:

A. The first position reflects the chamber(s) paced.

B. The second position refers to the chamber(s) sensed.

C. The third position refers to how the pacemaker responds to a sensed event

D. The fourth position reflects rate modulation, also referred to as rate responsive or rate adaptive pacing.

E. The rarely used fifth position specifies only the location or absence of multisite pacing, defined as stimulation sites in both atria, both ventricles, more than one stimulation site in any single chamber, or a combination of these.

The fifth position of the code is rarely used.

- "O" means no multisite pacing
- "A" indicates multisite pacing in the atrium or atria

Table 1: Revised NBG code for pacing nomenclature

Position	I	II	III	IV	V
Category	0 = None A = Atrium V = Ventricle D = Dual (A+V)	0 = None A = Atrium V = Ventricle D = Dual (A+V)	0 = None T = Triggered I = Inhibited D = Dual (T+I)	0 = None R = Rate modulation	0 = None A = Atrium V = Ventricle D = Dual (A+V)
Manufacturer's designation only	S = Single (A or V)	S = Single (A or V)			

Table 2: Different Mode of pacing of DDD

Clinical Condition	Atrial response	Ventricular response	Mode of Pacemaker
Sinus node is diseased but AV conduction is normal	Paced atrial rhythm	Intrinsic ventricular rhythm	A paced V sensed or AAI mode
Sinus node is normal but AV conduction abnormal	Sensed atrial rhythm	Paced ventricular rhythm	A sense V pace or VDD
Both sinus node function and AV nodal conduction abnormal	Paced atrial rhythm	Paced ventricular rhythm	A pace V pace or DDD
Atrial fibrillation with low ventricular rate	None	Paced ventricular rhythm	VVI(mode Switch)

- "V" indicates multisite pacing in the ventricle or ventricles
- "D" indicates dual multisite pacing in both atrium and ventricle

Depending on chamber sensed or paced, pacemaker can be classified in to three categories:

A. Single chamber pacemaker: Single chamber pacemaker can be of atrium based or ventricle based.

In atrial based or AAI pacemaker the single lead is located in right atrium (usually right atrial appendage). The response of the pacemaker to intrinsic atrial rhythm is inhibitory, if the pacemaker sense intrinsic sinus rhythm no stimulation is given by the pacemaker. If there is no intrinsic P wave after a specific time period after sensed or paced P wave (the specific time depends on the lower rate of pacemaker, i.e. if the lower rate is 60 , the time period is 1000 ms), the pacemaker will pace the atrium and a pacing artefact will be followed by P wave. This pacemaker is a preferred mode in presence of sinus node dysfunction; however concomitant AV nodal dysfunction is contraindication for this pacing.

In Ventricle based or VVI pacing the lead is poisoned in right ventricle (apex, septum or outflow). The response of the pacemaker is same as AAI except the fact that it senses the R wave and pace the ventricle and pacing response is pacemaker artefact followed by R wave. In absence of intrinsic R wave the ventricle is paced in a fixed rate irrespective of atrial contraction, the AV synchrony is not maintained. This is a preferred mode of pacing where AV synchrony is not required ie: in presence of permanent atrial fibrillation.

B. Double Chamber pacemaker: In double chamber pacemaker, the leads are located in Right atrium and ventricle. The Classical double chamber pacemaker is DDD pacemaker.

In absence of intrinsic sinus rhythm for specific period, the atrial lead paced the right atrium. Following the sensed or paced P wave the ventricular lead waits for a specific period(AV delay), if the intrinsic R wave occurs, the ventricular lead sense it and ventricular pacing is inhibited(Inhibitory response). However in absence of intrinsic ventricular contraction after specific AV delay, the Ventricle is paced by ventricular lead(Trigger response). The Pacing protocol of a DDD pacemaker in different electro pathological conduction is described in table 2.

C. In Multisite pacing apart from RA and RV lead, another lead is placed in coronary sinus to pace the left ventricle. As this pacemaker stimulates both LV and RV it is also known as biventricular pacemaker. This pacemaker is indicated in patients with heart failure

Pacemaker Follow-UP[5, 6]: A meticulous follow-up after pacemaker implantation is required for early detection and management of pacemaker related complications (pacemaker site infections, troubleshooting), optimizing the usage of pacing system, maximizing generator life and early assess battery status to predict end-of-life (EOL) of the pulse generator in order to permit timely elective generator replacement. Besides a pacemaker follow-up is used to provide patient and family support and education.

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

Table 3: Patient and device assessment	
1. Patient assessment	
A. Items to determine in a cardiovascular history	• Dizziness, syncope, palpitations, dyspnoea, 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
Device assessment	
A. 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)
B. Data from available telemetry (varies with manufacturer and model)	• Programmed settings including last programmed date • Battery status (cell impedance, voltage, energy, charge,current drain)
C. 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 useredefined criteria for data collection) • Lead impedance trends over time • Capture and sensing thresholds over time
D. If not available automatically	• capture and sensing threshold assessment

function. 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 12weeks time allows output reprogramming of the pacemaker settings to optimize safety margin and reduce battery drain. Thereafter till a period when the battery can be expected to deplete significantly or till about 7 to 10 years after the implant depending on the manufacturers recommendation and expected battery longevity. After that period 6 monthly follow-up is required till ERI is achieved. Once the ERI is achieved, a more intensified follow-up (3-6 monthly) is required. As per CSI/IHRS practice guidelines, factors tabulated in Table 3, should be included in pacemaker follow-up protocol.

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