Indication of Implantable Devices for the Prevention of Sudden Cardiac Death

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Introduction

In Japan, implantable cardioverter-defibrillators (ICD) were approved by the Japanese Ministry of Health, Labor and Welfare (MHLW) in 1996.1) The first guidelines for ICD were published by the Japanese Circulation Society (JCS) in 2001,2) then a revised version was posed on JCS’s website in 2006.3) Cardiac-resynchronization therapy without (CRT-P) with (CRT-D) implantable defibrillators were then approved in 2004 and 2006, respectively.1) The implantation of ICD, CRT-D and CRT-P are useful for improving the prognosis and/or sudden cardiac death event rate in patients with heart failure and/or fatal ventricular arrhythmias (ventricular tachycardia: VT/ventricular fibrillation: VF).4–11)

This review paper was written mainly to identify the indications for ICD/CRT-P or CRT-D on the basis of the 2006 JCS guidelines.3) Further, the usefulness of pharmacological tests for the choice of effective drugs to treat lethal arrhythmia and electrophysiological tests for prognosis, especially in patients with dilated cardiomyopathy, have been questioned recently.12) Thus, little attention was given to those factors in this paper. However, the presence structural heart disease and LVEF measurements were described in greater detail.

I. The implantation of secondary prevention for sudden cardiac death

The usefulness of the implantation of ICD in secondary prevention for the improvement of mortality and sudden cardiac death have been shown by the guidelines in western countries10) and several mega-trials.13) Since the recurrence rate of VT/VF was a very high 10 to 20% during two years in those patients, the implantation of ICDs were classified as a class I indication. Thus, we have to focus on the following class III indications (and contraindications) even in patients with ventricular arrhythmia.

1) Ventricular tachyarrhythmias due to a transient or reversible disorder (eg. acute ischemic disease, electrolyte imbalance, drugs) when correction of the disorder is considered feasible and likely to substantially reduced the risk of recurrent arrhythmias. 2) Incessant VT or VF not controllable by the appropriate drugs and/or catheter ablation. 3) VT or VF resulting from arrhythmia amenable to surgical or catheter ablation; for example, atrial arrhythmia associated with the Wolff-Parkinson Syndrome, and idiopathic VT. 4) Terminal illness with projected life expectancy less than six months. 5) Patients with significant psychiatric illnesses that may not cooperate with or accept device implantation. 6) NYHA Class IV drug-refractory congestive heart failure in patients who are not candidates for cardiac transplantation.

II. Implantation for primary prevention for sudden cardiac death

Implantable defibrillation devices (ICD/CRT-Ds) have several problems shared with standard pacemakers, such as trouble with leads, infection and infrequent operation-related complications.6,10) Further, the specific troubles associated with shock therapy, such as the aggravation of cardiac function14) (the factor of readmission, harm to the cardiac muscle and deterioration of cardiac function caused by the back-up pacing), the high cost, inappropriate shocks, in tolerance of shock therapy,15) and, finally, the difficulties associated with driving and the ability to work. Therefore, the primary prevention indications of these devices should be carefully considered. On the other hand, it have been reported that the implantation therapeutic devises was more effective in the improvement of mortality and sudden cardiac death than conventional drugs therapy.16,17) The first indication we should consider is whether or not patients have structural heart disease.
1. Indications of primary prevention implantation in patients without structural heart disease (Figure 1)

Patients without structural heart disease are counterindicated for shock device implantation, even if they have syncope and/or ventricular arrhythmia, excluding those with specific disease such as Brugada syndrome and congenital long QT syndrome. In this review, the indications in patients with Brugada syndrome and congenital long QT syndrome are according to the 2007 JCS guideline.18) Brugada syndrome was diagnosed as the spontaneous or drug-induced appearance of coved type ST elevation at the right precordial leads. The annual event rate in patients with asymptomatic Brugada syndrome was 0.5% in Japan,19) the indication of device implantation must be carefully considered because of the risk (although relatively low), the poor cost-effectiveness and the reduction of QOL. A history of syncope due to undetermined cause, a family history of sudden cardiac death, and ineffective use of β-blockers are considered to be risk factors for sudden cardiac death in asymptomatic Brugada syndrome. The indication of device implantation is class IIa when patients have ≥2 risk factors, and class IIb when patients have only one risk factor.18) (Figure 1)

The indication of primary prevention in patients with long QT syndrome is determined by the number of risk factors in patients with a history of syncope due to unknown cause, a family history of sudden cardiac death, and ineffective use of β-blockers. Similarly to the indication in patients with Brugada syndrome, the indication of device implantation is class IIa when patients have ≥2 risk factors, and class IIb in patients with only one risk factor. (Figure 1). There is no mention regarding counter indications (class III) of device implantation in patients with long QT syndrome.18)

There was no mention about the indications for family members of patients with idiopathic VF. We should consider the indication of ICD when VT/VF was inducible. Whether to counter indicate device implantation cold not be determined when VT/VF was not inducible in the patient.

2. Indications of primary prevention implantation in patients with structural heart disease

More than 80% of structural heart disease in patients with devices in Japan had old myocardial infarction or dilated cardiomyopathy. For this reason...
LVEF is considered as the most important predictive value of prognosis in those patients (Figure 1).

**LV dysfunction (LVEF \(\leq 35\%\)):** The indication of device implantation in patients with severe LV dysfunction (LVEF \(\leq 35\%\)) is classified as class IIa even if no ventricular arrhythmia is present. Though non-sustained VT and inducible VT/VF were high risk factors in patients with severely compromised LV function, ICD reduced the number of sudden cardiac death in patients with or without non-sustained VT and/or inducible VT/VF.

In the patients with LVEF \(\leq 35\\%\), drug resistant CHF (New York Heart Association; NYHA class III/IV), intraventricular conduction disturbance (a QRS width \(\geq 130\) ms) and with or without a history of fatal ventricular arrhythmias, the implantation of CRT-P or CRT-D were classified as class I indication.3) The degree of improvement of LV dyssynchrony by CRT-P or CRT-D had a good correlation to the prognosis. QRS width is the simplest method to assess LV dyssynchrony.20) The clinical applications of the pacing method known as CRT alone (CRT-P) began by using an epicardial lead in 1994.21) Recent meta-analysis11,22,23 demonstrated that CRT-P improved LVEF, QOL, and functional status, and reduced hospitalization for heart failure and mortality from all causes. However, it has not been determined whether CRT-P has a potential to suppress lethal arrhythmia or sudden cardiac death (Figure 2).

**LV dysfunction (LVEF 36\%–50\%):** There was no mention about the indication of device implantation in patients with moderate LV dysfunction (LVEF 36\%–50\%) in 2006 JCS guideline.3) Therefore, the patients with non-sustained VT and/or syncope of unknown etiology may be indicated for device implantation, when hemodynamically significant sustained VT/VF is induced. Further, for syncope of unknown etiology, device implantation is indicated in patients with cardiomyopathy even if VT/VF cannot be induced.

**LV dysfunction (LVEF >50\%):** ICD implantation may be indicated for hypertrophic cardiomyopathy as a structural heart disease in this category. Device implantation is indicated when patients have a history of syncope, non-sustained VT or sudden cardiac death in family, and VT/VF was inducible at electrophysiological study. From the report by Maron et al.,24) a single marker of high risk for sudden death may be sufficient to justify consideration for prophylactic defibrillator implantation in selected patients with HCM, because an important proportion of ICD discharges occurred in primary prevention patients who had undergone implantation for a single risk factor.

**References**

4) The antiarrhythmic versus implantable defibrillators

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<th>Weight</th>
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Figure 2 Results of the meta-analysis22) on the effects of CRT alone vs. control on sudden cardiac death.


